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POCKET SUPPLEMENT TO
PREAMBLE COMPILATION

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RADIOLOGICAL HEALTH

APRIL 1978-MARCH 1980

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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ACKNOWLEDGMENT

This publication was prepared under the overall direction of Agnes Black, Federal Register Writer, Food and Drug Administration, and the finished product reflects many hours of preparation, review, and quality control by Lola Batson, Marcia Rosenburg, and other members of the FRW staff.

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FOREWORD

All narrative preambles for this cumulative pocket supplement have been compiled from published Federal Register documents relating to the Radiological Health Regulations of the Food and Drug Administration, from April 1978 through March 1980.

Arranged to parallel the subject matter organization of Title 21 of the Code of Federal Regulations, this supplement is part of a comprehensive effort to make available to the public and the agency a central source for tracing the historical development of agency regulations by subject.

An agency User Review Committee conducts a technical oversight review of each volume and provides a potential user perspective to the decisionmaking process.

This cumulative pocket supplement to the original volume will be updated annually corresponding to the April 1 revision date of 21 CFR Chapter I. Notice of the availability of original volumes and pocket supplements will be published in the Federal Register upon printing.

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HOW TO USE THIS BOOK

The preamble compilation series is structured to follow the current organizational scheme for Food and Drug Administration regulations. It includes published final regulations, published proposals including proposals awaiting final action, significant proposals and final regulations that have subsequently been revoked, and substantive notice documents that relate to subsequent regulatory actions or certain statements of agency policy.

Certain classes of rule documents are excluded, including delegations of authority, organization statements, and fee documents.

Certain classes of "routine" documents are excluded. These are documents related to individual NADA's; food additives; GRAS affirmations; medical device classifications, standards, and premarket approvals; color additives; advisory committees; and antibiotic regulations. However, selected, major actions in these classes are included.

The outline and numbering system used in the preamble compilation is designed to establish an interrelationship between the original compilation and pocket supplements and has no relevance to the numbering systems used in the CFR; however, in most cases, the major subject groupings in the compilation parallel part designations in the CFR.

Documents appearing in the cumulative supplement are indicated with a dagger (†) in the revised table of contents for the supplement. All finding aids appearing in the supplement have been updated to include material in the original volume and the supplement.

This compilation reflects the correction of errors appearing in the original FEDERAL REGISTER publication. Page numbers have been inserted in the text to maintain the FEDERAL REGISTER page relationship to permit comparison between the compilation and original publication. No substantive changes have been made in any document; however, the original documents filed with the office of the FEDERAL REGISTER, rather than the published version of the document, represents the original source material for the compilation.

Any document pertinent to more than one subject area is marked with an asterisk (*) in the table of contents and appears in its entirety under each subject in the compilation series for the convenience of the reader.

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A. General Provisions

†6.—Accidental Radioactive Contamination of Human Food and Animal Feed

†6.1 Proposal—December 15, 1978

– 43 FR 58790 –

[21 CFR Part 1090]

[Docket No. 76N-0050]

ACCIDENTAL RADIOACTIVE CONTAMINATION OF HUMAN FOOD AND ANIMAL FEEDS

Recommendations for State and Local Agencies

AGENCY: Food and Drug Administration.

ACTION: Proposed Recommendations.

SUMMARY: This document provides guidelines and recommendations for action to be taken in the event of a radiological incident resulting in the contamination of human food or animal feeds. These guidelines and recommendations are for use by State and local agencies responsible for constructing response plans in the event of a radiological incident. The proposal would establish a set of guidelines that can be used to determine whether or not levels of radiation encountered in food after a radiological incident warrant protective action and would suggest appropriate actions that may be taken if action is warranted. This proposal is being made because the Food and Drug Administration (FDA) has a responsibility to issue guidance on appropriate planning actions necessary for evaluating and preventing radioactive contamination of foods and animal feeds and on the control and use of such products, should they become contaminated.

DATE: Comments by February 13, 1979.

ADDRESSES: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857; copy of supporting data to the Bureau of Radiological Health (HFX-440), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

G. D. Schmidt, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: The purpose of these proposed recommendations is to provide guidance to State and local agencies for use in the development of emergency plans and for use in the emergency response to incidents involving the contamination of food and animal feeds by radioactive materials. The guidance contains basic criteria, defined as protective action guides (PAG's), for establishing the level of radioactive contamination at which action should be taken to protect the public health and assure the safety of food. This document also proposes specific guidance on what emergency protective actions should be taken to prevent further contamination or restrict the use of food, as well as more general guidance on the development and implementation of emergency action. The protective action guides (PAG's) have been developed on the basis of a risk evaluation to identify that level of contamination where action is necessary to assure the safe use of food.

BACKGROUND

This proposed guidance on accidental radioactive contamination of food from fixed nuclear facilities, transportation accidents, and fallout is part of a Federal interagency effort coordinated by the Federal Preparedness Agency, General Services Administration. The Nuclear Regulatory Commission is the lead agency and among other activities has published a "Guide and Checklist for Development and Evaluation of State and Local Government Radiological Emergency Response Plans in Support of Fixed Nuclear Facilities" (NUREG-75/111 Dec. 1974).

The Federal Preparedness Agency issued a notice in the FEDERAL REGISTER of December 24, 1975 (40 FR 59494) which reflected governmental reorganizations and reassigned agency responsibilities for radiological incident emergency response planning.

Among the responsibilities of the Department of Health, Education, and Welfare (HEW) is "Issuance of guidance on appropriate planning actions necessary for evaluating and preventing radioactive contamination of foods and animal feeds and the control and use of such products should they become contaminated." Within HEW this function has been delegated to the Commissioner of Food and Drugs.

In the preparation of this proposal, FDA has reviewed the protective action guidance adopted by the Federal Radiation Council (FRC) (Refs. 8 and 9). The Federal Radiation Council was created to provide guidance to the Federal agencies on radiation protection standards.

Although the Federal Radiation Council no longer exists and its functions have been transferred to the Environmental Protection Agency (EPA), FRC expected that each Federal agency, by virtue of its immediate knowledge of its operating problems, would use the applicable FRC guides (Refs. 6 through 9) as a basis for developing detailed standards to meet the particular needs of the agency. Historically, recommendations on radiation protection have involved a judgmental analysis that balances the health hazards associated with radiation against the benefits of using radiation. These benefits include the use of radiation in industry, research, and diagnosis and treatment of disease, and in providing new sources of energy.

Scientific findings indicate that human exposure to radiation can induce genetic and somatic effects. Although current evidence is insufficient to prove with certainty the nature of the dose-effect relationship at low doses and dose rates (which are doses per unit of time) present radiation protection practice assumes a direct linear relationship between the probability of biological effect occurring and the amount of dose. By extrapolation from high-dose and dose-rate experimental and epidemiological data to low doses and dose rates, it becomes possible to estimate the probability of biological effects from low doses. It is generally agreed that the frequency with which an effect may actually occur will not exceed the frequency predicted by this assumption. In any case, a basic principle of radiation protection is to keep exposure to radiation as low as reasonably achievable.

The FRC guides (Refs. 6 through 9) have served as the basic guidance for control of environmental radiation.

Since the publication of these documents, data on radiation risks have been reviewed in light of additional information on biological effects that became available (Ref. 10), and environmental standards for nuclear power operations have been specifically defined by EPA (see the FEDERAL REGISTER of January 13, 1977 (42 FR 2858)). Thus, it is appropriate for FDA to issue response-planning recommendations which consider recent radiation risk and measurement data for use in the event of a contaminating radiation incident.

THE PROPOSED RECOMMENDATIONS

Proposed § 1090.400(b) defines a PAG as the projected radiation dose equivalent or dose commitment to individuals in the general population that warrants protective action following a release of radioactive material. Protective action would be warranted if the expected individual dose reduction is not offset by negative social, economic, or health effects. A negative impact could, for example, occur if an adequate alternative food supply is not available. The PAG does not include the radiation dose that has occurred before the assessment, nor do these recommendations imply an acceptable radiation dose from food containing radioactivity during normal

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conditions. Rather, their purpose is to prevent additional radioactivity from entering the human food chain and to reduce or avoid future radiation doses to the population after an accidental contaminating event. Such events include accidents at nuclear facilities, transportation accidents, and fallout from nuclear devices. The proposed protective actions are intended for implementation within hours or days from the time an emergency is recognized, and their duration should not be expected to exceed 1 or 2 months, based on previous experience with atmospheric fallout. Long-term regulation of radioactivity in the environment is the responsibility of the Environmental Protection Agency.

These recommendations would define projected radiation dose equivalent limits, exclusive of doses contributed by natural radioactivity, at which appropriate actions are suggested. The basic unit used in these recommendations is the radiation dose equivalent, defined in proposed § 1090.400(b) as "a quantity that expresses all radiation on a common scale for calculating the effective absorbed dose. It is defined as the product of the absorbed dose in rads and certain modifying factors. The unit of dose equivalent is the rem." "Dose commitment" means the radiation dose equivalent, delivered over a lifetime, from a single event received by an exposed individual to the organ cited. Ideally, if a particular tissue is subject to radiation from more than one source, the combined dose from all sources should be considered. However, in an accident at a fixed nuclear facility the food chain is likely to be the major route of significant population exposure (Ref. 1). For the purpose of these recommendations, the Commissioner has considered only the food pathway because FDA authority specifically relates to food and animal feeds. The proposed recommendations assume that the population group receiving radiation doses via the food chain receives only insignificant doses from other pathways, e.g., external radiation or inhalation.

PAG's are proposed in § 1090.400(c) for two levels of response:

1. Preventive PAG—applicable to situations where protective actions causing minimal impact on the food supply are appropriate. A Preventive PAG establishes a level at which responsible officials should take protective action to prevent or reduce the concentration of radioactivity in food or animal feed.
2. Emergency PAG—applicable to incidents where protective actions of great impact on the food supply are justified because of the projected health hazards. An Emergency PAG establishes a level at which responsible officials should isolate food containing radioactivity to prevent its introduction into commerce, and at which the responsible officials must determine whether condemnation or another disposition is appropriate.

Proposed § 1090.400(d) lists derived response levels in the following terms:

initial ground deposition (activity per unit of area), the concentration of radioactivity in milk (activity per unit of volume) or pasture (activity per unit of weight), and total dietary intake (total activity) that corresponds to these two PAG's. Thus, the derived response levels provide concentrations of specific radionuclides in specific media that can be directly compared to the levels of measured radioactivity to assure rapid and effective protective actions.

The recommendations in § 1090.400(e) provide guidance on the implementation of the PAG's for other food items, animal feeds, radionuclide mixtures, and other critical organs. The sampling sites are identified in § 1090.400(f), and references to recommended methods of analysis are provided in § 1090.400(g).

These recommendations proposed in § 1090.400(h) appropriate actions at Preventive and Emergency PAG response levels that are recommended within the context of the health benefit that may be achieved through the prevention of unnecessary radiation exposure.

PUBLIC COMMENTS

In the FEDERAL REGISTER of May 7, 1976 (41 FR 18897) the Commissioner invited interested persons to submit data, information, and views on guidelines for planning emergency response to radiological incidents that may result in radioactive contamination of human food and animal feeds. The Commissioner received and considered the following suggestions and views in preparing the proposed recommendations:

a. In radiation incidents involving a potential threat to the public health, recommendations in terms of specific radionuclide quantities, such as activity per unit volume or weight, are most easily applied.

b. Guidance should be based on evaluation of potential health risks associated with radiation levels at which protective action would be recommended and on cost-benefit analysis of various options available for preventing and reducing radiation exposure via the food pathway.

c. Proposed recommendations should be based on the potential radiation hazard to designated critical organs. They should consider the specific exposure and metabolic pathways, the radiobiological characteristics of individual radionuclides, and the radiosensitivity of the most critical group in the exposed population.

d. Proposed recommendations should be generally adaptable over a wide range of conditions, have a rapid response time, and be limited to the immediate emergency situation.

Based on responses to the May 1976 notice and other available data, proposed recommendations were drafted and distributed on December 7, 1976 to interested individuals, all States having radiological health programs, Federal agencies involved in radiological health programs, and Federal agencies involved in radiological emergency response planning. Some 24 respondents offered more than 100 pages of comments. A summary of the most pertinent comments and the Commissioner's response to them follows:

1. Many comments pointed out that responsibilities for formulating guidelines on radioactivity in foods seem to overlap, thus leading to an apparent duplication of effort. In general, these comments stated or assumed that the Environmental Protection Agency (EPA) was to set the PAG's; in fact, EPA has already done so for external radiation, i.e., radiation from fixed sources, and inhalation, i.e., airborne radiation, (Ref. 5). The comments nonetheless did recognize that setting guidance for foods falls within the purview of FDA. The consensus among the comments was that there should be cooperation between EPA and FDA, and that all Federal recommendations about radioactivity in foods and animal feeds should be compatible.

The Commissioner recognizes that several of the Federal responsibilities overlap. However, the Interagency Agreement (see the FEDERAL REGISTER of December 24, 1975 (40 FR 59494)), made EPA responsible for "Establishment of protection action guides in coordination with appropriate Federal agencies," and HEW responsible for

"Issuance of guidance on appropriate actions necessary for evaluating and preventing radioactive contamination of foods and animal feeds and the control and use of such products should they become contaminated." The Director, Bureau of Radiological Health, FDA, and the Deputy Assistant Administrator for Radiation Programs, EPA, established an official liaison to assure an exchange of opinion and information and to avoid a duplication of effort on the proposed FDA recommendations on radioactivity in foods.

2. Several comments requested a clarification of the relevance of prohibitions in section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to radioactive contamination of foods.

In the FEDERAL REGISTER of September 30, 1977 (42 FR 52814), FDA established procedures for regulating food contaminants and naturally occurring poisonous or deleterious substances in food. In § 109.6 (21 CFR 109.6) the Commissioner recognizes that when a food contaminant is unavoidable but cannot be approved under the criteria of section 409 of the act, a procedure to control its use under authority of sections 306, 402(a), and 406 of the act (21 U.S.C. 336, 342(a), 346) is still available. Accidental radioactive contamination of food for man or animals may fall within the scope of these provisions. Moreover, the Commissioner advises that establishing guidelines for radionuclide contamination of foods is required to meet HEW's responsibility as specified in the December 1975 notice. For these reasons the Commissioner concludes that such action is in complete accord with the act.

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3. Several comments asked whether milk containing radioactivity at a specific level could be diluted with milk at a lower radioactive concentration so the resultant product could be consumed.

There is a longstanding FDA policy against blending, which is the intentional adulteration of unadulterated food with contaminated or adulterated food (see generally 21 CFR Parts 109 and 509). It is the agency's position that blending adulterates the unadulterated food in violation of section 402(a)(1) of the act. The agency does, however, permit the diversion of contaminated human food into use as animal feed when such diversion would pose no significant risk to human or animal health. The Commissioner believes diversion of milk contaminated from a radiological incident should be considered on a case-by-case basis to evaluate the potential for ultimate contamination of human food and the risk to man and animals.

4. Some reviewers questioned the use of the linear nonthreshold hypothesis as a basis for risk analysis because they believe that it underestimates risk. A related comment suggested that both fatal and nonfatal health risks, and genetic as well as somatic effects, be examined to define each proposed PAG level.

The Commissioner believes the linear nonthreshold approach to somatic risk evaluation is the most prudent approach. Hence, the Commissioner is proposing that it be employed in these evaluations. Genetic risks were also considered, but the adequacy of existing data does not allow as precise an estimate of those risks. Also, nonfatal effects were not deemed valid as an endpoint for risk analysis because "health effects" and "ill health" are biological endpoints that are difficult, if not impossible, to quantify. In sum, the Commissioner concludes that the linear model is sufficiently conservative that it provides an adequate margin of safety for these nonquantifiable effects and has adopted it for assessing the risks of all health effects.

5. Several comments argued that the rationale for the PAG values (especially the Preventive and Emergency PAG's) were based on old information that could be replaced with newer data. These comments also suggested defining the PAG's in terms of the dose commitment to the critically exposed population (i.e., children less than 1 year of age), rather than a "suitable sample" (which in turn is defined as children less than 1 year of age). They proposed these definitions to avoid any confusion that "suitable

sample" might refer to food or animal feed rather than to human beings as intended in the draft (i.e., a "suitable sample" of the exposed population). Furthermore, use of a critically exposed population would eliminate the one-third factor used as an operational technique and associated with a projected dose to a "suitable sample" of the exposed population.

One comment stated that although the use of a "suitable sample" has historical precedence, its use was not adequately justified in the draft. Another reviewer suggested just the reverse; namely, that information applicable only to the operational technique concept and not the critically exposed population concept be cited in any recommendations. In any case, there is a consensus that a single defined exposed group should be selected as a basis for making the necessary calculations.

For the sake of simplicity and to be consistent with other Federal agency guidelines, the concept of a "suitable sample" is no longer employed. Rather, the Commissioner proposes to define PAG levels in terms of projected dose to an exposed individual in the critical segment of the population (i.e., persons receiving the greatest dose per unit intake and having the greatest sensitivity).

6. One reviewer recommended that the fetus be considered the critically exposed population for iodine-131.

The Commissioner advises that the problem has been evaluated by several investigators (Refs. 3 and 4), who found that the newborn infant and not the fetus has the highest iodine-131 uptake per gram of thyroid tissue. The Commissioner believes this group should constitute the critical segment of the population.

7. Several comments suggested removal or modification of the Alert PAG, which was included in the original draft, because:

a. Appropriate protective actions are not recommended.

b. The informational and administrative actions that are suggested are covered by other standards and regulations.

c. At times the major protective action at this level (e.g., control at source) is not possible within the framework of situations the recommendations are designed to cover, nor, as one reviewer points out, is this action within the scope of FDA responsibilities.

d. Sampling and analysis at the Alert PAG response levels would be difficult and expensive, especially on a nationwide basis.

e. The Alert PAG lends itself to misinterpretation by the public; if used, it should emphasize more strongly the extremely low levels of contamination it represents.

f. As presently conceived, the PAG's apply to an acute abnormal situation; the Alert PAG, evaluated in terms of chronic contamination (perhaps from normal operations) and long-term effects, is confusing when applied to abnormal situations. Further complications exist because the Alert PAG presents radionuclide concentrations in terms of average yearly concentration, while the other PAG's present the response level concentrations in terms of peak concentrations.

Based on these extensive comments, the Commissioner has deleted the Alert PAG concept.

8. Several comments noted that the problem of multiple contaminating events was not addressed in the December 1976 draft.

The Commissioner agrees that the draft recommendation did not directly address the possibility that the projected dose associated with a specific PAG could be exceeded by multiple events, each one of which by itself would not exceed the PAG. However, the proposed recommendation would express radioactivity in food in terms of total intake (microcuries) at which the projected dose would be equal to or exceed the PAG. The Commissioner believes this provides an option for the emergency planner to utilize in the event of multiple contaminating events.

9. One comment submitted evidence that the shelf life of milk can be extended by storage at lowered temperature, provided ultrahigh heat treatment is employed in processing.

The Commissioner has incorporated this procedure as a feasible protective action that will allow the decay of iodine-131 in contaminated milk.

10. One comment noted that the recommendations imply an ongoing routine sampling program capable of detecting levels of radioactivity associated with the PAG's. The comment asked whether such a system exists or whether FDA would assume responsibility

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for future operation of such a system.

The Commissioner advises that there is no extensive routine national program of sampling and analysis of radioactivity in food. As noted in paragraph 7 of this preamble, the Alert PAG has been deleted, and the recommendations no longer imply the need for an ongoing routine sampling program. In the event of an incident, the sampling programs required would be provided by State and local agencies and the nuclear facilities with the assistance of Federal agencies. This has been the agency's experience.

11. Another comment asked whether actions taken when the projected dose is exceeded are based on calculation from air concentrations from accidentally released radioactivity or from food that is actually contaminated.

The Commissioner notes that under the Federal Food, Drug and Cosmetic Act, action can be taken only on evidence that the food may be rendered injurious to health. In a protective action involving avoidance of projected doses, action may be appropriate based upon air concentration or ground deposition. However, action based solely on radioactive air concentrations is beyond the scope of these recommendations.

RATIONALE FOR THE PAG'S

The process of determining numerical limits for setting radiation standards has traditionally been one of risk ssessment. The process of risk assessment consists of two elements: Determination of the probability that an vent will occur, and determination of acceptable risk." Because initiation of rotective action assumes that an incient has occurred, the emphasis in this case will be on the determination f acceptable risk or safety. A recent discussion of acceptable risk defines risk as a measure of the probability and severity of adverse effects and defines safety as the degree to which risks are judged acceptable (Ref. 13). The Commissioner agrees that safety involves a judgment as to the acceptability of the risks but recognizes that there may not be universal agreement because various individuals may not all judge a given risk to be acceptable. Thus, the PAG's proposed here represent the Commissioner's judgment as to that level of contamination resulting from radiation incidents at which protective actions should be taken to protect the public health.

To provide a basis for this judgment, the risk of radiation exposure was compared to the risk of prevalent hazards accepted by society and to the variability of the natural radiation environment. The numerical dose commitment values that were derived are comparable to the risk from natural disasters (approximately a one in a million annual individual risk of death) and to the risk associated with two standard errors of the mean (the 95% confidence level) of the natural radiation environment in the United States (8.5 millirem per year). Both somatic risks (cancer deaths) based on an absolute risk model (Ref. 10) and genetic effects have been assessed in this evaluation. An absolute risk approach (estimates of deaths per rem of dose) was used in preference to a relative risk model because a relative risk model is based on natural cancer rates. Natural cancer rates are highly variable and depend upon such diverse factors as age, location, socioeconomic class, race, genetic makeup, and environmental factors.

For the Preventive PAG the most conservative estimates assume a dose commitment to the whole U.S. population that is associated with the somatic risk equivalent to two standard errors of the mean of the natural radiation environment. This statistic is a measure of the variability or scatter of the average doses of natural radioactivity amongst the states. These dose commitments are approximately 0.47 rem to the whole body, bone marrow, or other organs, and 1.4 rem to the thyroid.

In the case of the Emergency PAG, it is reasonable to expect a smaller population would be affected; and the value 15 million has been assumed, this being the estimated maximum population within 25 miles of present reactor sites. These population assumptions yield values for the Emergency PAG of 7 rem whole body, bone marrow and other organs, and 21 rem thyroid.

The procedures for estimating genetic risks are less precise than those for somatic risks, and it is therefore necessary to give a range for the genetic dose that is considered equivalent to the risk of two standard errors of the mean for natural radiation. The range of genetic dose values is 0.07 to 1.73 rem for the Preventive PAG and 1 to 24 rem for the Emergency PAG.

Risks can be compared to the risks from natural disasters for the purpose of determining their acceptability. The radiation doses equivalent to the risk for natural disaster (taken as one in a million annual individual risk of death) are 1.01 rem to the whole body or bone marrow for the preventive PAG and 15 rem for the emergency PAG. These values are quite consistent with the dose of 0.47 rem for the Preventive PAG and 7 rem for the Emergency PAG that are equivalent to the risk of two standard errors of the mean natural radiation dose.

To obtain some perspective of the economic impact of the PAG's as a function of the numerical level recommended, NRC performed a cost-effectiveness analysis using existing data. The cost-effectiveness analysis was done for two models based on projected incidents with different magnitudes of the radioactive release from light-water nuclear power plants. Under the limited scenarios investigated, the rate of change in costs for condemnation of milk drops rapidly when interdiction criteria are between a 0.5 and 10 rem dose commitment to the infant thyroid. The rate of change drops more gradually when the criteria are between 10 and 20 rem, and the rate of change only moderately drops following an interdiction criterion of greater than 20 rem.

The Commissioner concludes that it is prudent to recommend in proposed § 1090.400(c) numerical limits for the Preventive PAG equivalent to 0.5 rem dose commitment to the whole body, bone marrow, or other organs, and 1.5 rem dose commitment to the thyroid gland. Numerical limits for the Emergency PAG are recommended at 5 rem and 15 rem, respectively, representing a factor of 10 over the Preventive PAG.

In summary, the Preventive and Emergency PAG's refer to projected dose commitments to an individual in the exposed population. For the Preventive PAG the most critical segment of the population consists of newborn infants or children less than 1 year of age. For the Emergency PAG two critical segments are defined: (1) An infant group and (2) an adult group (excluding young children). This definition permits a greater flexibility in cases where exposure can be limited to adults only because children are more easily removed from the area of contamination or their diet limited to canned or other stored food.

APPLICABILITY

Proposed § 1090.400(a) applies the recommended PAG's to many types of contaminating events, including accidents at nuclear facilities, transportation accidents, and fallout from nuclear devices under peacetime conditions. Several radionuclides are considered particularly important and receive special attention in calculation of derived response levels. These are iodine-131, cesium-137, strontium-90, and strontium-89, which are relatively abundant among the fission products, enter the food chain easily, and are taken up and retained by the human body.

For transportation accidents the greatest hazard may be from the potential consequences of long-lived gamma emitters such as cobalt-60 and alpha emitters such as plutonium. For man, due to limited absorption through the gastrointestinal tract, these radionuclides are unlikely to have as great an impact through the human food chain as the radionuclides mentioned above; however, the proposed regulation refers to sources in the literature from which dose commitments to the gastrointestinal tract can be determined, should the need arise.

For other radionuclides not specified in the recommendations, the proposed response levels for the Preventive and Emergency PAG's may be calculated for individual radionuclides deposited on soil or pasture or present in milk or other foods based on dose commitment factors available in the literature (Refs. 2, 11, and 12).

Specific response levels are proposed for initial deposition, concentration in grazed forage and milk, and total radionuclide intake. The proposed recommendations suggest a method for relating individual food constituents to the total diet. Thus, response levels can be calculated for an appropriate PAG for individual foods that could be significant because of their relative proportion in the total diet by weight and/or high radionuclide concentrations.

Initial deposition on animal feeds, other than pasture, should be dealt with on a case-by-case basis, taking into consideration retention of the radionuclide in the particular feed and the relationship between radionuclide concentration in the animal feed and the concentration of radionuclides in human food. For hay or silage fed to lactating cows, the initial deposition should not exceed that equivalent to the recommendations for grazed forage (pasture).

SAMPLING

It is important that sampling be carried out at a site which permits sufficient time for action to be taken at an appropriate stage in the farm-processor-market cycle, and that the method of radionuclide measurement be predicated upon the specific response level. Proposed § 1090.400(f) recommends the retail market, processing plant, and farm as sampling sites. Proposed methods of measuring radionuclides in food and animal feeds recommended in § 1090.400(g) would meet the following criteria: (1) The complexity of the method decreases as the need for more rapid action increases; and (2) the sensitivity and selectivity of the method decreases with an increase in the level of detectability required. Methodology referred to in these recommendations includes precise, albeit complex, laboratory methods, rapid methods employing simple laboratory or modified field techniques, and field methods using a simple Geiger-Mueller detector. No action should be initiated without prior verification of the analysis.

PROTECTIVE ACTION

Protective action can be initiated at the source or at the beginning of the food chain (soil, vegetation, or cattle), applied to the intermediate vector prior to ingestion by man (milk or food), or administered to the population itself. For the purpose of these proposed recommendations the Commissioner expects specific actions would be limited to the food chain.

The most efficient protective action should be taken. Therefore, an attempt should be made to achieve a reasonable cost-benefit ratio.

The Commissioner emphasizes that prior to taking protective action, the responsible officials should weigh the health benefits to be gained from a reduction in radiation dose against the costs of disrupting the food supply. In this respect, the population to benefit from the dose reduction may not be the same as that receiving the impact. It is probable that both the State in which the contaminating event occurs and adjacent States may be involved; coordination among these affected jurisdictions would be essential and would require a knowledgeable consideration of all pertinent factors. Because this may involve a broad range of informed participation, the Commissioner recommends that if an action with a major impact is contemplated, the food processing and food distribution agencies and industries, as well as the health and agricultural agencies, be consulted. These recommendations envision that the contamination of food in the event of a radiation incident will be controlled at the State and local levels. However, should food in interstate commerce become involved, FDA will use these PAG recommendations as the basis for regulatory action.

REFERENCES

1. Baverstock, K. F., and J. Vennart, "Emergency Reference Levels for Reactor Accidents: A Re-Examination of the Windscale Reactor Accident," *Health Physics*. 30:339-344, 1976.

2. Cowser, K. E., S. V. Kaye, P. S. Rohwer, W. S. Snyder, and E. G. Struxness, "Dose Estimation Studies Related to Proposed Construction of an Atlantic-Pacific Interoceanic Canal with Nuclear Explosives: Phase I," Oak Ridge National Laboratories, ORNL-4101, 1967.

3. Dyer, N. C., and A. B. Brill, "Fetal Radiation Dose from Maternally Administered ^{59}Fe and ^{131}I," AEC Symposium Series No. 17, p. 73, 1969.

4. Evans, T. C., R. M. Kretzschmar, R. E. Hodges, and C. W. Song, "Radioiodine Upstake Studies of the Human Fetal Thyroid," *Journal of Nuclear Medicine*, 8:157-167, 1967.

5. Environmental Protection Agency, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," EPA 520/1-75-001, September 1975.

6. Federal Radiation Council, Memorandum for the President, "Radiation Protection Guidance for Federal Agencies," *Federal Register*, May 18, 1960.

7. Federal Radiation Council, Memorandum for the President, "Radiation Protection Guidance for Federal Agencies," *Federal Register*, Sept. 26, 1961, as corrected.

8. Federal Radiation Council, Memorandum for the President, "Radiation Protection Guidance for Federal Agencies," *Federal Register*, July 16 and Aug. 22, 1964.

9. Federal Radiation Council, Memorandum for the President, "Radiation Protection Guidance for Federal Agencies," *Federal Register*, May 22, 1965.

10. National Academy of Sciences, National Research Council, "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation," Report of the Advisory Committee on the Biological Effects of Ionizing Radiation (BEIR), 1972.

11. Ng, Y.C., C. A. Burton, S. E. Thompson, R. K. Tandy, H. K. Kretner, and M. W. Pratt, "Prediction of the Maximum Dosage to Man from the Fallout of Nuclear Devices, IV. Handbook for Estimating the Maximum Internal Dose from Radionuclides Released to the Biosphere, Lawrence Radiation Laboratory," UCRL-50163 Part IV, 1968.

12. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.109, "Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10 CFR Part 50," Appendix I, Oct. 1977.

13. Lowrance, W. W., "Of Acceptable Risk," William Kaufmann Inc., Los Altos, CA, p. 8-11, 1976.

Pertinent background data and information on the guidelines proposed herein are on file in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, and copies are available from the address above.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Public Health Service Act (secs. 301, 310, 311, 58 Stat. 691-693 as amended, 88 Stat. 371 (42 U.S.C. 241, 242o, 243)) and authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 1090 by establishing Subpart E consisting of § 1090.400, to read as follows:

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§ 1090.400

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[FR Doc. 78-34860 Filed 12-14-78; 8:45 am]

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†10.—National Standards for Medical Radiation Technologist Qualifications

†10.1 Notice of Intent—March 13, 1979

– 44 FR 14637 –

[Docket No. 78N-0416]

NATIONAL STANDARDS FOR QUALIFICATIONS OF MEDICAL RADIATION TECHNOLOGISTS

Intent to Propose Recommendations

AGENCY: Food and Drug Administration.

ACTION: Notice of Intent.

SUMMARY: The Food and Drug Administration (FDA) plans to develop recommendations on voluntary national standards for qualifications of medical radiation technologists. This notice is being issued because the FDA be-

lieves it is necessary to have the public participate in the process of developing the content and format of national standards and guidance on effective implementation of such standards.

DATE: Comments by July 11, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Charles Froom, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: Ninety percent of public exposure to man-made ionizing radiation results from medical procedures, primarily diagnostic x-ray examinations. The Food and Drug Administration (FDA) recognizes that much medical benefit is derived from diagnostic x-ray examinations, radiation therapy, and nuclear medicine procedures, but any radiation exposure may increase biological risk and any unnecessary exposure presents risk with no benefit. Regardless of equipment quality, medical radiation technologists (those individuals, other than licensed practitioners, who conduct diagnostic medical x-ray examinations, radiation therapy procedures, and nuclear medicine examinations) exercise considerable influence over patient exposure. The actions of these technologists directly affect the medical benefit as well as the radiological risk to the patient.

An estimated 130,000 to 170,000 persons operate medical diagnostic x-ray equipment in the United States. In addition, the medical radiation technologist workforce has approximately 10,000 persons employed in nuclear medicine technology and 2,000 in the field of ionizing radiation therapy.

The agency intends to develop recommendations on national standards for medical radiation technologist qualifications to help minimize unnecessary medical radiation exposure to patients by establishing appropriate criteria for the education and evaluation of competency of those who conduct such procedures. Although voluntary national standards have been developed by professional organizations, not all medical radiation technologists meet those standards, and where State standards exist, there are inconsistencies. Therefore, the agency proposes to develop recommended standards as "models" for use by teaching institutions, certifying organizations, other Federal agencies, and States. These recommendations would be implemented through educational programs and cooperative activities with professional organizations and State health agencies. Initial recommendations would address the qualifications of medical diagnostic x-ray personnel. Subsequent recommendations would address qualifications for radiation therapy and nuclear medicine technologists.

These recommendations will be developed by the FDA under the authority of section 356 of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263d) and sections 301 and 311 of the Public Health Service Act (42 U.S.C. 241 and 243). Section 356 of that act provides for the establishment and conduct of programs designed to protect the public health and safety from electronic product radiation and authorizes making recommendations where appropriate. Sections 301 and 311 of that act provide the broad responsibility to advise and promote cooperation between the States on matters relating to protecting the public against specified radiation hazards. The issuance of this notice of intent is part of the FDA policy of early public participation in recommendation-development activities.

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This notice of intent is also consistent with a 1977 Public Health Service Report, "Credentialing Health Manpower," (HEW Publication No. (OS) 77-50057). Recommendation II of the report states:

> National standards for the credentialing of selected health occupations should be developed and continually evaluated. Professional organizations, other elements in the

private sector, and State governments should play a significant role in this process. The standards thus developed should be utilized for the various purposes for which standards are required, including professional certification, licensure, private sector and civil service employment, and third party reimbursement.

To assist in developing the recommendations the agency invites comments and data supported by rationale concerning the following questions:

1. What effect, and to what extent, would model national standards for qualifications of medical radiation technologists have on radiation exposure of the patient? Please explain.

2. Are there effective alternatives to uniform national standards for qualifications of medical radiation technologist that can serve to promote the goals of: (a) improving performance of operators (both credentialed and non-credentialed) and (b) providing uniformity in standards (certification and licensure)? Please explain.

3. Does the present voluntary credentialing system ensure that only appropriately qualified operators perform medical radiation procedures? What evidence exists, either pro or con?

4. In those States that license technologists, have patient care and radiation practices been improved over the prelicensure conditions? What data exists, either pro or con? If patient care and practices have improved, is the improvement attributable to licensure, or have other factors played a deciding role?

5. What existing guidelines or standards could be considered in developing uniform model national standards? What exceptions or changes should be considered in any such existing guidelines or criteria?

6. Should continued competency requirements be considered in model standards? If so, what criteria and methods of competency assurance should be considered?

7. Should the recommended model standards include recognition for those individuals currently performing as medical radiation technologists, e.g., a "grandfathering" provision? If so, what provisions should be considered?

8. What effect would model national standards have on the availability, quality, and cost of medical radiation services if the standards were promulgated by standard-setting organizations? Please explain.

9. What other factors should be considered in developing model national standards (e.g., the economy, job market, etc.)?

10. Would existing standard setting organizations be likely to adopt a model national standard? To what extent?

11. How could model national standards be most effectively implemented? Would the benefits to be accrued from a national model outweigh the cost incurred by standard-setting organizations for administration of the recommended model standards?

12. Should the proposed voluntary standards be written to include qualifications for dental, ultrasonic, and microwave diathermy personnel?

13. Should the development of model national standards be expanded to include qualifications for those licensed practioners (e.g., physicians, dentists, chiropractors, podiatrists, and osteopaths) who themselves perform or supervise others performing medical radiation procedures? Please explain.

Interested persons wishing to provide information on these questions or other relevant topics for use in developing voluntary recommendations on model national standards for qualifications of medical radiation technologists may, on or before July 11, 1979, send their written comments, views, and data to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Four copies of all comments should be submitted, except that individuals may submit single copies of comments. Comments should be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Comments may be seen in the above-named office between 9 a.m. and 4 p.m., Monday through Friday. The recommendations that are drafted after considering the comments will be proposed in the FEDERAL REGISTER, and further public comment will be invited.

This notice of intent is issued under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 356, 82 Stat. 1174-1176 (42 U.S.C. 263d)) and under authority delegated to the Commissioner (21 CFR 5.1).

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[FR Doc. 79-7252 Filed 3-12-79; 8:45 am]

C. Guidelines For Specific Products

†3.—Dental Post-Treatment Radiographs

†3.1 Proposal—July 17, 1979

– 44 FR 41486 –

[21 CFR Part 1000]

[Docket No. 79N-0086]

Dental Post-Treatment Radiographs; Proposed Recommendation

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing a recommendation to discourage insurance carriers from requiring post-treatment dental radiographs. This practice could result in patient radiation exposure that does not have a health care benefit that justifies the radiological risk. This proposal is a part of the agency's effort to minimize unnecessary exposure of the public to ionizing radiation.

DATE: Comments by September 17, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Alex Martin, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: Under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.), FDA's Bureau of Radiological Health (the Bureau) conducts and supports research, training, and operational activities to minimize unnecessary exposure of the public to electronic product radiation. In carrying out this purpose, FDA is authorized to make recommendations relating to the control of electronic product radiation that the agency considers appropriate. Accordingly, FDA proposes to add new § 1000.60 (21 CFR 1000.60) to provide an official recommendation discouraging the use of dental post-treatment radiographs by third-party carriers (insurance companies or insurance groups) to justify claims. In 1973, some third-party insurance carriers developed policies requiring post-treatment radiographs as a claim reimbursement prerequisite, to control problems of fraudulent claims and unsatisfactory dental care. Dental societies, State and Federal government organizations, and others interested in radiological health became concerned because such policies require patient exposure to radiation regardless of its clinical necessity or applicability. Moreover, it can be argued that some other means of claims verification, such as random spot-checking of patients by an independent dentist for the insurance carrier, is a more effective approach to detecting false claims or of assessing poor dental care. This is particularly true because radiographs can be substituted for one another without easy detection.

The Bureau first became involved in the problem of third-party carrier requests for post-treatment dental radiographs during 1973 to 1974 in Pennsylvania, where a major dental insurance carrier planned to require post-treatment dental radiographs for insurance claims. Meetings and conferences were held with personnel from the Bureau, the Pennsylvania State Health Department, the Pennsylvania Dental Society, and Pennsylvania Blue Shield for the purpose of developing acceptable guidelines for the use of dental radiographs by insurance carriers. The problem of excessive carrier demand for post-treatment dental radiographs was diminished largely because of the efforts of those attending these cooperative meetings. The major accomplishment was a modification of the dental carriers' requirements for post-treatment radiographs. However, no formal policy on this issue was published by FDA or the Bureau.

The agency is not aware of current insurance company requirements that radiographs be submitted as proof for dental insurance claims. Since 1973, the demand for dental insurance has increased considerably and continues to rise. The American Dental Association (ADA) estimates that 35 to 40 million Americans were covered by privately sponsored dental care plans in 1977. In early 1978, ADA projected that the number would reach 60 million by 1980. (See, for example, the ADA Leadership Bulletin, Volume VIII, No. 5, February 27, 1978.) Only a year later, in February 1979, ADA estimated the 60 million mark had already been passed. (See ADA News, February 19, 1979.) Thus, it is possible that, with the rapid increase in numbers of people covered by dental insurance, the demand for monitoring dental insurance claims by post-treatment x-rays may rise again.

FDA believes that the use of dental radiographs merely to monitor dental treatment claims for reimbursement constitutes a source of unnecessary radiation exposure to the population. Justification for each x-ray exposure requires that there be some potential benefit to the individual receiving it. X-ray examinations performed for diagnostic reasons in the normal course of dental care are beneficial to the patient when the radiographs are carefully evaluated by the dentist in view of the patient's symptoms and individual dental care needs. However, post-treatment dental radiography is essentially a screening procedure that is not based on a patient's dental care needs. In those instances where a post-treatment dental x-ray examination is indicated, the decision to perform it should be made only by the patient's dentist. This philosophy is consistent with the directive "Radiation Protection Guidance to Federal Agencies for Diagnostic X-Rays" issued by the President in the FEDERAL REGISTER of February 1, 1978 (43 FR 4377).

Although fraudulent claims and substandard dental care, to the extent that they occur, directly or indirectly harm patients and society and should be discouraged, that discouragement should not entail a radiological risk to

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patients without a benefit to each patient.

The proposed recommendation would provide guidance to dentists, organizations responsible for administering dental care, and third-party carriers responsible for reimbursing the provider of dental care. The proposed recommendation has been reviewed and endorsed by the Bureau's Medical Radiation Advisory Committee (MRAC), an advisory committee established under section 222 of the Public Health Service Act (42 U.S.C. 217a). It advises FDA on formulation of policy and development of coordinated national programs relating to optimal applications of ionizing radiation for medical and dental purposes. Comments by MRAC members as well as additional comments by other interested persons about the proposed recommendation have been placed on file with the FDA Hearing Clerk, address below.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 356, 82 Stat. 1174-1175 (42 U.S.C. 263d)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 1000 be amended by adding new § 1000.60 to read as follows:

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§ 1000.60

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[FR Doc. 79-21805 Filed 7-16-79; 8:45 am]

5.—Radiation Exposure of Women of Childbearing Age

†5.2 Proposal—November 20, 1979

- 44 FR 66616 -

[21 CFR Part 1000]

[Docket No 75N-0340]

Procedures To Minimize Medical X-Ray Exposure of the Human Embryo and Fetus; Recommendations for Medical Radiation Exposure of Women of Childbearing Potential

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: In an effort to reduce unnecessary radiation exposure to the entire population, the Food and Drug Administration (FDA) is proposing recommendations intended to minimize the irradiation of the human embryo and fetus from diagnostic x-ray procedures. X radiation and other types of ionizing radiations are associated with a variety of harmful effects in the human embryo and fetus. Some of them may occur as a result of diagnostic x-ray procedures. The agency is proposing to establish recommendations for attending physicians, consulting radiologists, x-ray equipment operators, and patients that:

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(1) emphasize the importance of ascertaining whether the patient is or may be pregnant prior to referral for examinations that may include the uterus in or near the primary x-ray beam; (2) suggest alternatives for physicians in managing the patient who is or may be pregnant at the time of the contemplated x-ray referral request; and (3) suggest methods for reducing medical x-ray exposure of fetuses throughout gestation.

DATE: Comments by March 20, 1980.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Joseph Wang, Bureau of Radiological Health (HFX-460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: Under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.), the Bureau of Radiological Health of the Food and Drug Administration conducts and supports research, training, and operational activities to minimize unnecessary exposure of the public to electronic product radiation. In carrying out this purpose, the agency is authorized to make such recommendations relating to the control of electronic product radiation as it considers appropriate. Accordingly, FDA proposes to add new § 1000.51 (21 CFR 1000.51) to provide recommended procedures for minimizing medical x-ray exposure of the human embryo and fetus.

Experimental studies with animals and some limited human epidemiological studies and case reports have indicated that x-ray exposure presents a hazard to the unborn child. The magnitude and kinds of possible effects of radiation exposure depend upon the amount and type of ionizing radiation received and the stage of fetal development when exposure occurs.

The scientific literature supports the conclusion that at no time during gestation can the developing embryo or fetus be irradiated without incurring some risk of a biological effect. The first trimester of pregnancy, especially the first 2 weeks after conception, carries the highest risk of abortion induced by radiation. Radiation exposure of the fetus during all stages of pregnancy has been associated with an increased incidence of leukemia and other childhood cancers, but there is some suggestion that the carcinogenic effect is greatest for exposure during the first trimester. Additionally, during the second and third trimesters, fetal irradiation can be associated with developmental effects manifested by physiological and behavioral changes, some of which may not become apparent until later in life.

Because both the maternal and fetal gonads may be exposed, abdominal irradiation during any stage of pregnancy may also produce alterations in genetic material in at least two individuals. Furthermore, abdominal irradiation of a prospective mother prior to conception may result in genetic changes that could be transmitted to her offspring; for example, some controversial evidence has suggested an increased risk of mongolism and cancer in children born to mothers receiving x-ray examinations prior to conception.

It has been estimated that, in 1970 (the last year that x-ray utilization data are available for the United States), 805,000 pregnant women in the United States (23 percent of all women having live born infants that year) received x-ray examinations of all types (Ref. 1). Of these, an estimated 298,000 received abdominal area x-rays that directly irradiated the fetus. Nearly 22,000 fetuses were irradiated during the first trimester, and it is estimated that 7,000 may have been exposed in the first month of pregnancy.

Calculations based on cancer risk data from the Oxford Survey of Childhood Cancers (Ref. 2), imply that each annual use of prenatal abdominal examinations at these rates could result in approximately 19 extra cases of childhood cancer each year for the next 15 years. Therefore, the estimated number of cancers due to irradiation at any time during pregnancy would be 285 cases per year at equilibrium in children under 15 years of age. Of these 285, perhaps 22 would be due to irradiation during the first trimester. The additional cancer cases would only be observed at equilibrium (15 years after irradiation of the population begins) and not in the first year. Conversely, it would take 15 years to reduce the number of extra cancers to zero if all examinations during pregnancy were abruptly eliminated. Stated in individual terms, there is a cumulative probability of about 1 in 1,000 that a child who was irradiated in utero by an abdominal x-ray examination of the mother, consisting of 2 to 3 radiographs, will develop cancer during the first 15 years of life, based upon the Oxford Survey data. For individuals who receive larger doses (as might be the case in fluoroscopy), the estimated risk would be increased proportionately, assuming a linear dose-effect relationship. The risk due to radiation exposure cannot be decreased to zero, however, because x-ray examinations required for the clinical management of the patient cannot be eliminated.

In addition to an increased risk of childhood cancer, prenatal irradiation may be associated with subtle mental, physiological, and genetic changes that are difficult to detect and measure. It is important to note that environmental stresses may modify the biological response to radiation. For example, the human embryo and fetus have been shown to be particularly susceptible to a variety of chemicals, drugs, viruses, and other physical agents. One or more of these agents could influence the effects of irradiation, thus altering the foregoing risk estimates.

The agency believes however, the risks of harmful effects that may occur as a result of diagnostic x-ray procedures are small in comparison to many risks in everyday life that are commonly ignored. Thus, exposure risks should not be a deterrent to x-ray examinations judged necessary for the medical care of women who are or could be pregnant. Nevertheless, these risks are finite and actions can be taken to mitigate them within the bounds of sound medical care.

An advance notice of proposed rulemaking concerning medical radiation exposure of women of childbearing potential was published in the Federal Register of December 15, 1975 (40 FR 58151). In response to this notice, 76 comment letters were received from physicians, hospital administrators, radiological physicists, technologists, and private citizens. From questions that appeared in the Federal Register notice, a summary of the comments and the agency's conclusions are as follows:

1. Is it advisable to schedule nonemergency radiological examinations of the abdomen of women of childbearing age only during the early part of the menstrual cycle? If such scheduling is appropriate, should this be done only when the examination could be deferred until term if a pregnancy is observed or suspected at the time the examination is scheduled to occur?

The majority of comments favored scheduling of nonemergency abdominal x-ray examinations during the early part of the menstrual cycle. Several comments, however, opposed elective scheduling on the ground that it is impractical. Several persons noted that there is no "safe" period during which a radiological examination could be undertaken. If a patient is to be examined even though she is found to be pregnant, scheduling serves no useful purpose and may even be counterproductive. Furthermore, if an examination can be postponed to the end of a pregnancy, there is the question of the need for the examination, even if the patient is not pregnant.

The agency believes that detailed guides for the use of elective scheduling may not always be appropriate. Thus, the proposal recommends that emphasis be placed primarily on ascertaining the pregnancy status of women with childbearing potential prior to their referral for abdominal x-ray examinations so that physicians can give due consideration to possible pregnancy in making their referral decisions. In this regard, the agency advocates that attending physicians use x-ray consultation forms that provide information on the patients' pregnancy status.

2. Is it feasible to modify radiological examinations of known or possibly pregnant women, e.g., fewer views and different technique factors, to reduce exposure of the embryo or fetus? If so, under what circumstances? To what extent does this result in an unacceptable loss of diagnostic information?

With regard to the feasibility of modifying radiological examinations of known or possibly pregnant women, most comments said that it was possible to modify the number of films and projections to provide protection of the fetus. Comments also stated that modifications should be determined in consultation with the radiologist to achieve acceptable diagnostic information.

The agency encourages consultation between the attending physician and the radiologist to determine any examination modifications that may be made if the referring physician suspects a pregnancy or knows that the patient is pregnant. However, no generalizations can be made regarding examination modifications because the techniques used in an examination will vary according to each patient's need.

3. Is it advisable to recommend to institutions that the physician ordering the examination indicate on the referral slip whether or not the patient is or could be pregnant?

Most comments agreed that it is advisable for the attending physician to indicate on the referral slip whether or not the patient is or could be pregnant. Although several respondents noted that patients within the childbearing age group are usually queried as to their pregnancy status, a number of radiologists stated that pertinent clinical information is often lacking on the referral slips.

The agency believes that x-ray consultation forms, when fully completed, can be an effective tool in assuring that the referring physicians have tried to ascertain whether their patients are or could be pregnant. Furthermore, the agency believes that patients should be encouraged to inform the attending physicians and x-ray department personnel that they are or may be pregnant.

4. Is it advisable to recommend to institutions that the physician ordering the examination indicate on the referral slip whether he or she would be satisfied with a limited study, i.e., modified from the routine manner of performance, on a patient known or suspected to be pregnant?

Several comments objected to the agency establishing recommendations that the physician ordering the examination indicate whether or not a limited study would be satisfactory. It was, however, considered good medical practice to encourage consultation between the radiologist and the referring physician so that appropriate diagnostic information could be provided to contribute to the patient's care. The proposed recommendation, therefore, encourages consultation between the radiologist and referring physician to determine on an individual basis whether or not limited studies are warranted.

5. For which abdominal x-ray examinations could fetal shielding be em-

ployed without compromising the diagnostic value of the radiograph?

Several comments provided examples of the types of abdominal examinations that could be performed using fetal shielding. Other comments claimed that any use of fetal shielding during abdominal examinations would only decrease diagnostic accuracy. The agency believes that the determination of whether or not to use fetal shielding, once the examination has been deemed immediately necessary, requires judgment by the radiologist on a case-by-case basis.

6. To what extent do pelvimetry examinations affect decisionmaking in the management of delivery?

Most comments stated that pelvimetry examinations have negligible influence in the management of delivery. Others declared that they are useful when abnormalities of the birth canal or fetal position are suspected. Several comments noted that the use of pelvimetry is declining. The efficacy of this procedure was questioned in a 1975 FDA study that extracted information on the indications for and benefits of pelvimetry as the examination was performed in selected hospitals (Ref. *3*). Campbell (Ref. *4*) and Joyce et al. (Ref. *5*) also studied the use of pelvimetry. Campbell's study cast significant doubt on the usefulness of pelvimetry, and Joyce et al. stated that routine pelvimetry should be performed only in the following cases: (a) antenatally, for singleton breech presentations in primigravid and multigravid patients; (b) postpartum, after a caesarean section, difficult forceps delivery, or perinatal death, when vaginal delivery might be considered in a subsequent pregnancy; (c) before pregnancy, after the healing of a fractured pelvis or at some suitable point in the management of other relevant orthopedic disorders.

A pelvimetry panel, composed of members of the American College of Obstetricians and Gynecologists and the American College of Radiology, with the assistance of the Bureau of Radiological Health, has considered the available evidence concerning the usefulness of the pelvimetry examination and is in the process of drafting recommendations regarding its use. When they are completed, the recommendations will be tested in clinical practice and further evaluated.

7. How much radiation exposure is received by the embryo or fetus from various diagnostic nuclear medicine procedures?

Several comments provided data on the radiation exposure received by the embryo or fetus from various diagnostic nuclear medicine procedures. Others noted that the exposure varies greatly with the radiopharmaceutical involved and with the age of the fetus.

It is usually possible, however, to calculate the absorbed radiation dose to the embryo or fetus from diagnostic nuclear medicine procedures using currently available techniques and dose models. These calculations and a determination of the necessity of the procedure need to be made on an individual case basis if nuclear medicine procedures are being considered for a pregnant or potentially pregnant patient.

8. With what frequency are nuclear medicine diagnostic procedures performed on women of childbearing age?

The frequency with which nuclear medicine diagnostic procedures are performed on women of childbearing age was reported in the comments to range from 10 percent to "quite common."

A data collection system, called Medically Oriented Data System (MODS), operated by the Medical Data Systems Staff of the Office of the Director, Bureau of Medical Devices, Food and Drug Administration, provides frequency data as a service to FDA operating programs. Data from MODS now show that approximately 58 percent of persons undergoing nuclear medicine procedures in the United States are women and, of these, 29 percent are of childbearing age.

9. How useful is nuclear medicine placental scanning in the medical management of pregnant women?

The unanimous response to this question was that ultrasound has replaced nuclear medicine for placental imaging.

It is generally agreed that the biological effects to the fetus resulting from nuclear medicine procedures are not well known. Until additional information becomes available on low-dose effects from such procedures, the agency believes that recommendations on this subject should be limited to ways to minimize medical x-ray exposure of the human embryo and fetus.

Following the analysis of comments on the December 15, 1975 notice, a report entitled "Clinical Methods of Avoiding Medical X-Ray Exposure of the Human Embryo and Fetus: A Technical Overview" was prepared by the Bureau of Radiological Health, Food and Drug Administration (Ref. *1*). The report was reviewed by the Bureau's Medical Radiation Advisory Committee and other interested and knowledgeable parties who were invited to comment on its contents.

The recommendations proposed here represent the concepts discussed in the report as modified in response to reviewer comments. A copy of the Technical Overview and other pertinent background data on which the agency relies in proposing these recommendations are on file with the Hearing Clerk, Food and Drug Administration.

The Bureau has also discussed significant elements of the proposed recommendations with the American College of Obstetricians and Gynecologists (ACOG), the American College of Radiology (ACR), and the National Council on Radiation Protection and Measurements (NCRP), which have all issued their own policy statements or recommendations. Although there are some variations depending on the perspective of the issuing organization, there do not seem to be any important conflicts between the FDA proposed recommendations and the recommendations of these other groups. The ACOG states that there is no measurable advantage to using scheduling as a general procedure (Ref. 6); the ACR discourages elective scheduling as a general procedure. (Ref. 7); and the NCRP suggests use of a decision tree for scheduling or postponing elective examinations of the abdomen or pelvis of women of childbearing capacity (Ref. *8*).

Discussion

FDA shares responsibility (e.g., with radiologists), to minimize radiation exposure of the population from medical radiologic examinations, consistent with deriving needed diagnostic information. Although the risk of harm to an individual from these examinations is very small, the public health impact of this risk when applied to large populations can be significant. For any one woman, the risk of injury to her unborn child due to an abdominal area x-ray examination is too small to deter a necessary medical examination. ("Abdominal area examination" means any examination in which the uterus is in or adjacent to the primary x-ray beam, e.g., examinations of the hip, pelvis, lower abdomen, lower back.) It should be noted that nonabdominal examinations, when conducted with appropriate technique factors, collimation, and abdominal shielding, contribute only a negligible exposure to the embryo or fetus. Nonabdominal examinations are, therefore, not included in the proposed recommendations.

The proposed recommendations and rationale for them are as follows:

1. Proposed § 1000.51(b)(1) states that the attending physician should ascertain the likelihood of pregnancy when considering nonemergency abdominal area x-ray examinations for a woman who could be pregnant at the time of the consultation request. X-rays and other types of ionizing radiation have the potential to cause biological effects in the human embryo and fetus. Because of these effects on the human embryo and fetus, every effort to avoid unnecessary x-ray exposure is encouraged. In some cases this exposure might be avoided if the physician is aware that the patient is or might be pregnant.

2. Proposed § 1000.51(b)(2) recommends that x-ray consultation forms be used to provide a method to heighten the attending physician's awareness of the need to determine the pregnancy status of the patient prior to requesting an abdominal area x-ray procedure. In the absence of a notifi-

cation by the attending practitioner, the x-ray personnel should ask the patient if she might be pregnant prior to conducting an abdominal area examination.

This recommendation is based on studies that show that women are often selected for abdominal area x-ray examinations without being questioned as to their pregnancy status (Refs. *9* and *10*). Annotated consultation requests have been mentioned as one method of assuring that attending physicians determine whether patients who may be pregnant at the time of the abdominal area examination request are, in fact, pregnant. An annotated consultation request should provide, at a minimum, appropriate space for the attending physician to indicate whether the patient is, is probably not, or may be pregnant. Some institutions may also wish to include information on whether or not the examination should be performed irrespective of pregnancy status, whether the physician would like to consult the radiology department about the possibility of modifying the requested examination, or whether the examination could be postponed for a time. Space may also be provided on the annotated consultation request for the attending physician to note the date of the patient's last menstrual period. The consultation request can be a permanent record of the consideration of pregnancy if it is appropriately filed and can be retrieved.

As an alternative to recording pregnancy information on the consultation request, it has been suggested that the attending physician record this information on the patient's chart. This procedure preserves the privacy of the patient in that the consultation request may reveal the possibility of pregnancy to hospital staff who are not involved in the patient's immediate medical care. However, recording pregnancy information on the patient's chart may not be sufficient to alert the radiologic technologist who performs the examination to seek authorization to use special measures to reduce the x-ray exposure of the embryo or fetus, e.g., a grid with lower than usual ratio, fetal shielding, or fewer than the normal number of views.

3. Proposed § 1000.51(b)(3) recommends that, in consultation with the radiologist and based upon the patient's individual needs, any of the following alternative courses of action might be appropriate for the attending physician when it is discovered that the patient being considered for an abdominal area x-ray examination is or is likely to be pregnant.

(a) The attending physician may decide to cancel a contemplated abdominal area examination once aware that the woman is or may be pregnant. The potential health benefit to be gained from a contemplated examination can be variable, depending upon the attending physician's degree of conviction of the necessity for the examination. If the attending physician is convinced that the x-ray procedure is medically necessary, then the patient's pregnancy should not deter the examination. If there is less certainty of the necessity for the examination, the attending physician may not wish to proceed with the examination, once aware that the woman is or might be pregnant.

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(b) The attending physician may request a modified or limited examination which would, as a minimum, provide the necessary clinical information with the least possible radiation exposure. Under certain circumstances, an abdominal area x-ray examination involving fewer exposures or more restricted views than usual may be used by the radiologist to provide the necessary clinical information with less x-ray exposure. Whether modification of a routine x-ray procedure is in the best interests of the mother's and child's health must be decided on an individual basis. The attending physician is, therefore, encouraged to consult with the radiologist.

Ultrasound procedures may replace or supplement certain x-ray examinations. However, experimental and epidemiological studies to date have not ruled out the possibility of biological risk from ultrasound during pregnancy. Consequently, in the absence of additional information, ultrasound procedures should not be viewed as an entirely risk-free alternative to x-ray procedures. Attending physicians and radiologists are encouraged to discuss the relative clinical value of ultrasound procedures under specific clinical circumstances.

(c) The attending physician may request the x-ray examination regardless of pregnancy status. This option is a logical alternative in situations when the woman's medical circumstances dictate an immediate need for an examination, regardless of whether she is pregnant.

(d) In the case of a known pregnancy, the attending physician may assess the possibility of deferring the examination until later in pregnancy or until term. As discussed in the rationale for proposed § 1000.51(b)(1), the embryo or fetus is at risk of different types of radiation-induced injury throughout gestation. However, there is evidence that the carcinogenic effect is greatest when irradiation occurs during the first trimester. This option recognizes that there are some abdominal area examinations which, although necessary, may be deferred for a time long enough into pregnancy so that the risk to the fetus or embryo is appreciably reduced. In some cases the examination might even be deferred until term, eliminating all x-ray exposure risk to the embryo or fetus.

(e) In the case of a possible but unconfirmed pregnancy, the attending physician may defer an examination that is not needed immediately until pregnancy is ruled out, until later in pregnancy, or until term (see option (d)).

Sometimes called elective scheduling, this option involves scheduling nonemergency abdominal x-ray examinations of women of childbearing potential during the early part of the menstrual cycle (usually the first 10 to 14 days) to minimize the possibility of irradiating a newly fertilized egg. The examinations suitable for this approach are those few that could safely be postponed if the woman subsequently were found to be pregnant. This course of action offers guidance in the management of those rare cases in which (1) the woman's pregnancy status is undetermined, (2) she needs an abdominal x-ray examination, and (3) the examination could be postponed until later in the pregnancy when the fetus is less radiosensitive if she later proved to be pregnant. It must be stressed that this option should be considered only in the unusual simultaneous occurrence of these three circumstances. Furthermore, examinations should be scheduled as soon as possible after the expected onset of menses. Because the date of ovulation varies considerably among women, scheduling an examination as early as possible after the onset of menses minimizes the possibility that a woman will become pregnant prior to the examination.

Some institutions and individual practitioners have applied elective scheduling to all women of childbearing potential without discriminating between examinations that could not or could be postponed to a later period in pregnancy or after delivery. This practice could present the practitioner with a dilemma—if the woman is pregnant, either forego an examination essential to the management of the woman's condition or risk irradiating the embryo during organogenesis when it is especially vulnerable to radiation-induced damage to developing organ systems. Because of the hazards of this situation, the International Commission on Radiological Protection and the National Council on Radiation Protection and Measurements stress that the few examinations for which elective scheduling can be used are those that can be safely deferred until the latter half of pregnancy or until term if the patient is found to be pregnant at the time of her scheduled visit to the x-ray facility.

There are other problems associated with elective scheduling. The examination date is scheduled based upon the woman's last period. If the woman has irregular periods or is reluctant to discuss them for whatever reason, scheduling an examination becomes difficult. Once scheduled, the woman may jeopardize her own health by not returning for the examination. Obviously, elective scheduling is not a comprehensive approach to the problems of irradiation of the fetus, but, in the restricted circumstances to which it applies, elective scheduling is an alternative worthy of consideration.

4. Proposed § 1000.51(b)(4) recommends that a patient who is or thinks she might be pregnant should alert her attending physician as well as x-ray facility personnel prior to the performance of an x-ray examination. At the same time, medical personnel should impress upon their patients the importance of volunteering this information.

This recommendation is based upon the principle that the patient has the right to participate in decisions regarding her medical care. Commensurate with that right is the patient's responsibility to communicate important information to health care personnel, including her pregnancy status, to help assure optimum medical management. The patient should also inform her physician about any recent similar x-ray examinations. A new examination may not be needed if a recent one can provide the necessary diagnostic information. Finally, if she knows that she is scheduled to receive an x-ray examination of the abdominal area, the patient should postpone a planned pregnancy until after the examination.

The following information has been placed on file in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m. Monday through Friday.

References

1. U.S. Department of Health, Education, and Welfare, Public Health Service, Food and Drug Administration, Bureau of Radiological Health,"Clinical Methods of Avoiding Medical X-Ray Exposure of the Human Embryo and Fetus: A Technical Overview," November 1976.

2. Bithell, J. and Stewart, A., "Prenatal Irradiation and Childhood Malignancy: A Review of British Data from the Oxford Survey," *British Journal of Cancer*, 31:271-278, 1975.

– 66621 –

3. Kelly, K. M., et al., "The Utilization and Efficacy of Pelvimetary," *The American Journal of Roentgenology*, 125:1, 66-74, September 1975.

4. Campbell, J. A., "X-ray Pelvimetry: Useful Procedure or Medical Nonsense," *Journal of the National Medical Association*, 68:514—520, November 1976.

5. Joyce, D. N., et al., "Role of Pelvimetry in Active Management Of Labour," *British Medical Journal*, 4:505—507, November 1975.

6. The American College of Obstetricians and Gynecologists, Statement of Policy, Guidelines for Diagnostic X-Ray Examination of Fertile Women, May 1977.

7. Brown, R. F., Prepared Remarks for the October 20, 1976 American College of Radiology Press Conference, October 1976.

8. National Council on Radiation Protection and Measurements, Medical Radiation Exposure of Pregnant and Potentially Pregnant Women, NCRP Report No. 54, July 1977.

9. "X-Ray Safety," *The Lancet*, p. 905, April 19, 1975.

10. Asire, A. J., Murray, J. L., Linton, O. W., "Trends in Maternal X-Ray Exposure Practices in the San Francisco Bay Area," Unpublished Report Available from O. W. Linton, American College of Radiology, 6900 Wisconsin Ave., Chevy Chase, MD 20015.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 356, 82 Stat. 1174—1176 (42 U.S.C. 263d)) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that 21 CFR Subchapter J be amended in Part 1000 by adding new § 1000.51 to Subpart C, to read as follows:

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§ 1000.51

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[FR Doc. 79-35631 Filed 11-19-79; 8:45 am]

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†7.—Radiation Exposure Recommendations for Diagnostic X-Ray Examinations

†7.1 Notice—August 17, 1979

– 44 FR 48354 –

[Docket No. 79N-0156]

Radiation Exposure Recommendations for Diagnostic X-Ray Examinations

AGENCY: Food and Drug Administration.

ACTION: Notice of Inquiry.

SUMMARY: The Food and Drug Administration (FDA) is considering development of radiation exposure recommendations for diagnostic x-ray examinations. Radiation exposure appears to vary widely for the same procedure performed at different facilities, with some patients receiving too much radiation and other so little than the diagnostic information being sought may not be obtained. The agency is requesting further information before beginning to develop recommendations for such radiation exposure.

DATE: Comments, data, and information by December 17, 1979.

ADDRESS: Written comments, data, and information to the Hearing Clerk (HFA—305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Raymond F. Coakley, Jr., Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: FDA may develop radiation exposure recommendations for diagnostic x-ray examinations through its Bureau of Radiological Health (BRH) and under the authority of the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.). FDA conducts and supports research, training, and operational activities to minimize unnecessary exposure of the public to electronic product radiation. In carrying out this purpose, FDA is authorized to make such recommendations for the control of electronic product radiation as the agency considers appropriate. In this capacity, the agency is considering the development of radiation exposure recommendations for diagnostic x-ray examinations. The impetus for establishing these voluntary recommendations comes from several sources:

1. The Nationwide Evaluation of X-Ray Trends (NEXT) program has consistently demonstrated wide variation in the x-radiation entrance skin exposure that would be received by a standard-size patient undergoing the same diagnostic x-ray procedure at different medical facilities.

2. Data from two BRH programs (Dental Exposure Normalization Technique (DENT) and Breast Exposure—Nationwide Trends (BENT)) indicate cases of radiation exposure both so low and so high that the diagnostic usefulness of the radiograph may be impaired.

3. Two States have established exposure limits for certain x-ray procedures. Illinois, in its "Rules and Regulations for Protection Against Radiation" (1974), included radiation exposure limits which consist of tabletop exposure values per radiograph for four commonly performed medical x-ray procedures: Vermont has instituted legislation (effective December 10, 1977) establishing entrance skin exposure criteria or limits for eight diagnostic views. Several other States are developing exposure guidance for individual diagnostic x-ray procedures either as regulations, recommendations or educational guides.

4. The Presidential document on Radiation Protection Guidance to Federal Agencies for Diagnostic X-Rays, published in the FEDERAL REGISTER on February 1, 1978 (43 FR 4377), includes specific radiation exposure guides for 10 diagnostic x-ray examinations (projections).

5. The BRH Medical Radiation Advisory Committee (MRAC) recommended in February, 1977 that BRH study the feasibility of developing recommendations concerning ranges of skin exposure of organ doses per exposure for diagnostic radiology examinations. MRAC is a committee established pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a). This committee advises on the formulation of policy and the development of coordinated national programs relating to the use of ionizing radiation in the healing arts.

The wide variety of exposures used to obtain satisfactory radiographs seen in the NEXT data indicates that some patient exposures are greater than necessary. By contrast, low exposure levels, observed in the DENT and

BENT program data entail the risk of an unsatisfactory radiograph and the necessity for an additional exposure (i.e., a repeat). A range of exposures defined by both upper and lower limits appears advisable. Satisfactory diagnostic x-ray examinations should be obtainable within this range.

To assist in the study and in the development of useful recommendations, the agency specifically invites scientific and technical data, as well as comments or suggestions supported by detailed rationale and justification, on all of the following concerns:

1. Should radiation exposure recommendations be developed and published for diagnostic x-ray examinations? Are there better alternatives to protect the public from unnecessary x-radiation? How should recommendations be published?

2. Can useful recommendations be developed? What information and data exist either to support or to refute the feasibility of establishing exposure recommendations?

3. What might be the impact of voluntary exposure recommendations? How would they affect the development of technology, e.g., development of faster image receptors or of higher-exposure techniques that yield greater diagnostic information? How would they affect dose reduction, image quality, and cost?

4. How could the recommendations be reevaluated and updated in light of improvements in equipment and procedure? Should the recommendations be made only for very specific combinations of equipment, procedure, and patient characteristics? How should the recommendations be affected by developments in technology?

5. How broad or narrow should the recommendations be? Should they include all radiographic views or a selected few? Should they address radiography only or fluoroscopy as well? Should they be developed for different film screen combinations and grid usage or expressed in general terms, which may indirectly require certain image receptor and grid combinations? Should they be specified as a function of the x-ray beam quality (i.e., x-ray spectrum, kilovolt peak potential, and/or half value layer)? Should they refer to a "standard patient" or address the range of patient sizes found in actual practice? For any answers to these questions, please give a rationale.

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6. What values should be provided by these recommendations and how can they by determined? How can the associated diagnostic adequacy be determined? Would upper and lower limits of exposure be more useful than maximum exposure limits only? What exposures should be addressed: Entrance skin exposure, midline dose, specific organ dose, image receptor dose? If fluoroscopy were addressed, how would variables such as x-ray beam on-time, field size, output, etc. be taken into account?

7. Should the recommendations be established for individual views or for the total exposure in specific examinations? If the former, how would exposure recommendations for an individual view restrict the amount of diagnostic information in that view? If the latter, how would total exposure recommendations restrict the number of views and the total amount of diagnostic information?

8. How could the recommendations be used? How would facilities verify continued operation within the recommendations? Would recommendations provide the most efficient means for a facility or a radiation control agency to identify potential radiation exposure problems?

Individuals or organizations wishing to receive draft copies of these recommendations or related documents may have their names placed on the mailing list by writing to the Division of Compliance (HFX-460), Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Interested persons are invited to participate in developing the proposed recommendations by submitting written comments or data on the subject. Communications on the proposed recommendations should be identified with the docket number appearing in brackets in the heading of this document and should be sent to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65. 5600 Fishers Lane, Rockville, MD 20857 before December 17, 1979. Four copies of all comments should be submitted, except that individuals may submit single copies. Comments received after this deadline may be considered, depending on the stage of development of any recommendations. Any recommendations that are developed will be published in the FEDERAL REGISTER as proposals and public comment will be invited.

This notice is issued under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 356, 82 Stat. 1174-1176 (42 U.S.C. 263d)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1).

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[FR Doc. 79-25276 Filed 8-16-79; 8:45 am]

10.—Facilities Quality Assurance

†10.2 Proposal—April 28, 1978

– 43 FR 18207 –

[21 CFR Part 1000]

[Docket No. 76N-0145]

DIAGNOSTIC RADIOLOGY FACILITIES QUALITY ASSURANCE PROGRAMS

Proposed Recommendation

AGENCY: Food and Drug Administration.

ACTION: Proposed Recommendation.

SUMMARY: This is a proposed recommendation for quality assurance programs for operators of diagnostic radiology facilities as part of the agency's efforts to minimize unnecessary exposure of the public to electronic product radiation. This action is being taken because data from several sources indicate that many diagnostic radiology facilities are producing poor quality images and giving unnecessary patient radiation exposure.

DATE: Comments and data by October 25, 1978.

ADDRESS: Written comments to the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Charles P. Froom, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2436.

SUPPLEMENTARY INFORMATION: Under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.), the Bureau of Radiological Health of the Food and Drug Administration (FDA) (hereafter "the Bureau") conducts and supports research, training, and operational activities to minimize unnecessary exposure of the public to electronic product radiation. In carrying out this purpose, the Commissioner of Food and Drugs is authorized to make such recommendations relating to the control of electronic product radiation as he considers appropriate. Accordingly, he proposes to add new § 1000.55 (21 CFR 1000.55) to provide a recommendation that health practitioners and others responsible for the operation of diagnostic x-ray facilities establish quality assurance programs in such facilities.

The performance standard for diagnostic x-ray equipment (21 CFR 1020.30 through 1020.32) is intended to assure that medical and dental diagnostic x-ray equipment is manufactured and installed so as to minimize unnecessary or unproductive radiation resulting from its use. The goal of this proposed recommendation is to encourage diagnostic radiology facilities to voluntarily establish quality assurance programs for all equipment components of the facility, not just those addressed by the standard. The Commissioner believes that facility-based programs would, through adequate monitoring and maintenance, keep at a minimum unproductive patient radiation exposure produced by the equipment after installation. In addition, such programs will help assure that the facility produces good quality diagnostic images and may reduce facility operating costs. Thus the proposed recommendation, through voluntary actions, would expand and extend the impact of the performance standard.

THE NEED FOR QUALITY ASSURANCE PROGRAMS

Information from several sources indicates that in many cases diagnostic radiology facilities are producing poor quality images and giving unnecessary radiation exposure. An early indication of the need to promote diagnostic radiology quality assurance programs was revealed by such information, including a study of the radiographs submitted to the National Institute of Occupational Safety and Health (NIOSH) under its Pneumoconiosis Compensation Program. To qualify to participate in this program, facilities must be certified by NIOSH as being competent. As evidence of competence, sample chest radiographs, information on the equipment used, and the qualifications of the technologists must be submitted to NIOSH. If a facility is certified, the radiographs are read at the facility (A readers) and by members of the departments of radiology of three major medical centers (B readers). If the A and B readers disagree, the radiographs are sent to the department chairman of one of the three major medical centers (C readers), whose decision is final. In addition to being certified as competent, the A readers must win approval either through attending a 2-day training seminar held jointly by the American College of Radiology and NIOSH or by submitting six radiographs showing various stages of pneumoconiosis along with their interpretations. Despite the screening of facilities and readers for competence, Trout, et al., found that 44 percent of the certified facilities examined had from 10 to 40 percent of their submitted radiographs rejected by the B or C readers as being of inadequate quality for the diagnosis of pneumoconiosis (Ref. 1).

Image quality problems were also seen in a study of pre-authorization dental radiographs submitted to Pennsylvania Blue Shield. A preliminary evaluation found that at least 50 percent of the films were not adequate to determine the efficacy of the proposed treatment. A more detailed followup investigation found 55.3 percent of the full mouth series and 53.6 percent of the partial mouth series radiographs to be technically unsatisfactory (Ref. 2).

Poor image quality is not limited to just dental and pneumoconiosis radiographs. A representative of a major film manufacturer reported that the general radiographic facilities with which the manufacturer had worked rejected on the average 13 percent of the facilities' radiographs as being of inadequate quality (Ref. 3).

The authors of these studies listed the reasons why the images were considered to be of inadequate quality. Some of these reasons were related to difficulties that could be eliminated or reduced by adequate quality assurance programs in the diagnostic radiology facilities. Other studies also indicate that electrical or mechanical problems exist with a large percentage of the x-ray units examined (Refs. 4, 5, and 6). These electrical and mechanical difficulties may lead to poor image quality. Quality assurance programs have the potential of detecting and correcting these problems also.

The effect of poor quality images is twofold. If the image is not of optimum quality then the practitioner does not have the maximum amount of diagnostic information available to him. The chance of making a wrong diagnosis or of not detecting an abnormal condition is increased. In addition if the quality of the radiograph is so poor that the examination must be repeated, the patient will have received unproductive radiation exposure during the original examination.

Unnecessary radiation exposure may also be received by the patient in the production of those radiographs that do not have to be repeated. Data from the Bureau's Nationwide Evaluation of X-Ray Trends (NEXT) program revealed that the "standard patient" (as defined within Ref. 7) would have received widely different exposures depending upon the facility, or even the machine within a facility, at which the examination was received (Ref. 8). A

Bureau analyst has suggested that this variation could be reduced by adequate facility quality assurance programs (Ref. 9).

In total, the above studies identified problems of poor image quality and unnecessary patient exposure in diagnostic radiology facilities. Evidence from two additional studies supports the Bureau's conclusion that facility-based quality assurance programs could correct or at least reduce these problems. A Bureau study conducted in cooperation with the Radiology Department of the Public Health Service hospital in Baltimore showed that a quality assurance program limited to automatic film processors reduced by 30 percent the number of retakes required because of poor image quality of the original radiograph (Ref. 10). The major film company study cited above reported that the facilities that adopted quality assurance programs for the entire facility were able to reduce their rejection rate from an average of 13 percent to an average of 7 percent (Ref. 3). Reducing the number of rejected radiographs of course means a reduction in unproductive radiation exposure. The Commissioner believes it is reasonable to conclude that a program that reduces the need for retakes would also improve the quality of the radiographs actually read, and the diagnostic information available to the practitioner would thereby be increased.

An FDA analyst has estimated the potential nationwide reduction in patient dose due to facility-based quality assurance programs. Depending on the number of radiographs produced, the dose reduction from reducing the number of repeated radiographs in hospitals alone could range from 209,000 to 333,000 rems of active bone marrow dose or 195,000 to 333,000 rems of whole body dose annually (Ref. 11). Programs leading to fewer retakes in nonhospital facilities would add to this total as would the elimination of unnecessary radiation exposure in the production of the radiographs actually read in both hospital and nonhospital facilities. The Commissioner concludes that quality assurance programs would thus reduce the U.S. population's health hazard arising from unproductive radiation exposure.

The Commissioner believes that quality assurance programs in diagnostic radiology facilities may also lead to savings in operational costs. A study conducted at the University of Alabama at Birmingham estimated that a savings of $37,000 per year over personnel costs was attributable to the University's quality assurance program (Ref. 12). The Birmingham facility includes 26 radiology examination rooms and produces about 300,000 radiographs a year. Thus the net savings due to quality assurance was about $12,000/100,000 radiographs. The Bureau's Baltimore study indicated that a hospital taking 100,000 radiographs a year could expect to save at least $6,000 a year from a film processor quality assurance program alone (Ref. 10).

The need for diagnostic radiology quality assurance was discussed by the Bureau with its Medical Radiation Advisory Committee (MRAC) beginning in January 1974. In accordance with MRAC recommendations, the Bureau initiated quality assurance activities that were further endorsed in May 1975 by the committee. These activities included collecting information on current quality assurance efforts, testing additional techniques for identifying and correcting quality assurance problems, and examining ways to promote quality assurance programs in diagnostic radiology facilities.

As a result of these activities, it was concluded that the most effective way of promoting facility quality assurance would be by an educational approach. The value of such an approach was seen by the success of the Bureau's Dental Exposure Normalization Technique program in reducing patient exposure while maintaining or improving diagnostic quality in dental radiology. This recommendation is intended to be part of this educational approach. It will urge that facilities establish quality assurance programs and will suggest elements to be included in the programs.

RESPONSE TO ADVANCE NOTICE

In the FEDERAL REGISTER of May 7, 1976 (41 FR 18863), the Commissioner issued an advance notice of intent to propose recommendations for quality assurance programs for diagnostic radiology facilities. Substantive comments were received from 8 professional organizations, 7 government agencies, 6 manufacturers of x-ray or quality assurance equipment, and 23 individual radiologists, physicians, medical physicists, technologists, and engineers. A summary of the general comments

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and the Commissioner's conclusions are as follows:

1. One comment contending that recommendations were unnecessary stated that "present State regulations are sufficient to assure quality in diagnostic x-ray facilities."

The Commissioner's review of existing State regulations and radiation control activities does not in general support this conclusion. However, efforts will be made to coordinate Federal and State activities in the quality assurance area with the assistance of the Quality Assurance Task Force of the Conference of Radiation Control Program Directors.

2. Four comments supported the concept of facility quality assurance programs but were concerned about practical problems. One comment believed that the cost of such programs would be too great for individual practitioners unless assistance was available from State agencies, professional groups, or medical schools. The other comments suggested that there is a shortage of trained quality assurance personnel.

The Commissioner concludes from his review of the quality assurance activities of the Bureau, State agencies, and private groups that efforts are already under way to solve these practical difficulties.

3. Ten comments supported the concept of facility quality assurance programs but expressed the opinion that certification, licensing, or other mandatory requirements might eventually be required for the success of these programs. Eight respondents, however, who believed that the voluntary approach should be tried first, are not in disagreement with the value of a recommendation.

4. The remaining comments supported the need for diagnostic radiology quality assurance programs and the issuing of a recommendation. Eighteen respondents who described their personal experience with quality assurance programs all believe their programs to be of value, although one mentioned that the program had not been operating long enough for full evaluation.

The Commissioner's analysis of the comments made on the benefits of quality assurance programs follows:

a. Several comments indicated that they believed quality assurance programs in diagnostic radiology facilities would reduce patient radiation exposure. A survey of the diagnostic radiology departments of osteopathic hospitals, conducted by the Committee of Government Affairs of the American Osteopathic College of Radiology, also generally supported this conclusion. Of the 50 responding facilities, nearly all asserted that quality assurance would reduce patient exposure and would also improve diagnostic image quality.

b. Some comments stated that radiation exposure to healing arts personnel would be reduced.

c. Other comments agreed with the majority of responses to the osteopathic hospital survey, that consistent or improved diagnostic image quality would result. Some of these comments also indicated that, in addition to maintaining or improving diagnostic results, quality assurance programs would indirectly improve health care by minimizing inconvenience to the patient and by making it easier to evaluate new products.

d. The majority of comments discussing the impact of quality assurance on medical costs agreed that costs would be eventually reduced, although there might be an initial increase due to equipment purchases and adoption of the quality assurance routine. The few comments that suggested costs would increase acknowledged that this would be compensated by the benefits of such programs.

e. Several comments supported the conclusions of the previously mentioned Bureau's Baltimore study which cited fewer repeated radiographs as a major reason for cost reduction (Ref. 10). Others cited this reduction in retakes as a major reason for the expected reduction in patient exposure. Yet others suggested savings on repairs and improved planning for equipment purchases as sources of cost reduction.

In addition to inviting comments on FDA's intent to propose recommendations for quality assurance programs, the May 7, 1976 advance notice announced the availability of publications providing information on quality assurance programs and procedures. Over 1,200 requests for one or more of these publications have been received from individuals associated with a great variety of medical, industrial, and government organizations. This widespread interest, as well as the comments cited above, has encouraged the Commissioner to propose this recommendation for quality assurance programs in diagnostic radiology facilities.

INTENT OF PROPOSED RECOMMENDATION

The Commissioner intends to encourage all diagnostic radiology facilities to establish quality assurance programs. In addition, the recommendation will provide the organizational framework for these programs by describing the elements which they should include. However, it is recognized that different types of diagnostic radiology facilities have different needs and resources. Thus, although proposed § 1000.55(a) and (b)(1) advises that quality assurance programs are needed whenever an x-ray system is used to irradiate humans for diagnostic purposes, the recommendation suggests that the extent to which each element of the program is implemented should be determined by an analysis of the facility's specific objectives conducted by its personnel or by qualified outside consultants. The flexibility provided a facility by allowing it to determine the extent of its program based upon its own analysis of need will allow that facility to match its investment to resources while still selecting useful program techniques. Factors affecting this analysis would include the size of the facility as well as the types of examinations conducted.

RELATIONSHIP OF THE RECOMMENDATION TO OTHER QUALITY ASSURANCE ACTIVITIES

The variety of diagnostic radiology equipment in use and its ever changing nature would make it impractical to keep detailed instructions for quality assurance procedures up to date in the Code of Federal Regulations. Therefore proposed § 1000.55 will identify these procedures only in a general way. Information on the specific procedures will be provided by other Bureau and nongovernmental activities. These activities also include the provision of resources for training quality assurance personnel and the provision of consultative services to the facilities thus answering the concerns of some of the comments on the advance notice. In total, these activities and the recommendation make up the educational approach to solving the problems of poor image quality and unnecessary radiation exposure.

Among the other Bureau quality assurance activities is the development of information on specific procedures through pilot programs such as the Bureau's Baltimore study (Ref. 3). The results of such pilot tests will be published as they become available. The Bureau has also sponsored seminars in which active quality assurance programs were discussed and has supplied transcripts of these seminars to interested parties. Publication of a series of quality assurance manuals is planned and the first of these, dealing with automatic film processors, has been released. A Diagnostic Radiology Quality Assurance Catalog listing equipment, training, and publications available to help facilities implement their programs has been assembled. A slide/tape training program entitled "A Basic Program of Quality Control for the Automatic Processor" is currently being developed for radiologic technologists and will be followed by other training programs for technologists. In cooperation with the State radiation control agencies, the Bureau has developed and conducted consultative quality assurance programs to assist facilities in dealing with specific problem areas. All of these activities will provide detailed guidance in support of the recommendation.

Further information is available through the activities of various professional organizations on their own initiative and in association with the Bureau. The American College of Radiology has undertaken projects to investigate the reliability of radiographic equipment and to alleviate the problem of poor radiographic quality in the NIOSH Pneumoconiosis Compensation Program. An American College of Radiology Committee on Quality Radiographs has been established to develop programs and guidance to improve the quality of clinical diagnostic radiology. This committee, with the Bureau's support, is sponsoring a series of conferences dealing with specific problems. The Bureau also is assisting the American College of Radiology in testing a quality assurance kit.

The American Association of Physicists in Medicine has established a task force that, with the support of the American College of Radiology and the Bureau, is writing a recommended protocol for quality assurance tests. The American Dental Association and its local units have actively supported the Bureau's Dental Exposure Normalization Technique program. The International Chiropractors Association has sponsored a series of workshops for its members dealing with quality assurance and radiation protection. The Council on Roentgenology to the American Chiropractic Association has published guidance for their members which deals in part with quality assurance. The Commission on Radiology of the Federation of Chiropractic Licensing Boards is developing several programs to provide training and assistance to chiropractors in the implementation of quality assurance procedures. As the first step in making recommendations, the American Osteopathic College of Radiology has surveyed its members concerning current quality assurance practices. The American Society of Radiologic Technologists has offered training in quality assurance methods at its national and local meetings and in the past has encouraged attendance by giving Evidence of Continuing Education credits. Several x-ray equipment and film companies have also devoted considerable effort to developing quality assurance procedures and to training health personnel.

The Commissioner concludes that these government and private activities will provide adequate information on the specific procedures to be conducted in a diagnostic radiology facility quality assurance program.

Discussion of Recommendation

Proposed § 1000.55(a) and (b)(1) makes clear that quality assurance programs are needed in any facility in which an X-ray system is used to irradiate humans for diagnostic purposes.

Proposed § 1000.55(b) defines several terms to alleviate their currently conflicting uses. The major definitions in § 1000.55(b) were discussed in the advance notice and apparently have been accepted. That notice should be consulted for examples of quality control techniques and quality administration procedures. The Commissioner advises that although the definition of what constitutes "high" quality has been left to the facility, the Bureau will continue its efforts to develop an objective means of determining radiograph quality. When available, such techniques will aid the facility in establishing acceptability limits.

Proposed § 1000.55(c)(1) stresses the Commissioner's belief that responsibility is central to the success of a quality assurance program. Several comments in response to the advance notice indicated that administrative problems presented greater difficulties in facility programs than did the availability of adequate monitoring and corrective techniques. A clear assignment of responsibilities, with authority to carry out such responsibilities, would help to solve this difficulty. Proposed § 1000.55(c)(1)(i) through

(iv) suggests possible allotments of responsibility, developed in part from the Bureau's views on what is needed for an effective quality assurance program and in part from comments received in response to the advance notice.

If the equipment does not operate properly to begin with, the task of the quality assurance program is obviously made more difficult. The importance of purchase specifications, and especially of testing to determine whether newly installed equipment meets these specifications, was demonstrated by one respondent to the advance notice who had recently tested 50 new X-ray rooms after the equipment was adjusted to the satisfaction of the vendor. Not one of the rooms met the purchase specifications without further adjustment. Data in another comment showed that requiring equipment to meet purchase specifications before acceptance reduced the need for servicing after acceptance. With respect to some parameters, the provisions of § 1020.30 will provide a starting point for the writing of purchase specifications. For parameters not addressed by the standard, however, the facility staff, acting perhaps through its Quality Assurance Committee, should evaluate its needs as recommended in proposed § 1000.55(c)(2).

Traditionally, purchase specifications have been basically performance specifications. Recently, some facilities have reported that including performance specifications in the initial announcement to prospective vendors limits their choice of equipment. These authors (Refs. 13 and 14) found it to be of more value to initially describe the capabilities the equipment must have and to ask vendors to supply performance specifications for their equipment capable of performing these functions. The authors also report that this approach usually leads to more vendors bidding and thus gives them a greater choice of equipment. However, the Commissioner believes that even if initial specifications do not include performance specifications, the final written purchase specifications should state desired performance levels, and proposed § 1000.55(c)(2) so provides.

A number of parameters of the X-ray system which may require monitoring have been suggested in the open literature, by the Bureau's programs, and in comments on the advance notice. The list of parameters in proposed § 1000.55(c)(3) is a compilation from these sources. The wide variety of diagnostic radiology facilities and their equipment prevents the Commissioner from suggesting a definitive list for all facilities. He urges each facility to evaluate its own situation and select parameters that it needs to monitor, whether from the list or from other sources.

The consensus of the comments, which listed in order of importance the components of the X-ray system for monitoring purposes, was that the highest priority should be given to monitoring the image processor. This priority was based upon both the likelihood that difficulties would arise with the processor and the availability of monitoring techniques for that component.

Proposed § 1000.55(c)(4) recommends that facilities adopt definite, and where possible, objective standards of acceptable image quality. The Commissioner has concluded that without such standards, interpreting findings will be difficult, and responsible personnel will be uncertain as to when corrective measures are required.

Proposed § 1000.55(c)(5) emphasizes the importance of ongoing evaluations of both equipment performance and effectiveness of the facility's quality assurance program. The Commissioner believes such evaluations are required to determine corrective action needs, to justify the continuation of the program, and to adjust the techniques and procedures to meet new situations, thus increasing program effectiveness. Evaluating equipment performance should be based where possible on monitoring results, although the opinions of technologists and radiologists will also be useful in detecting the presence of malfunctions if not their causes. Other useful procedures for evaluating the effectiveness of a quality assurance program, suggested both by Bureau experience and by response to the advance notice, include studies of the number and basis for retakes, the number of minimally acceptable but poor radiographs, repair costs, records of unscheduled maintenance, or comparison of the monitoring results over a period of time. Finally, a number of comments mentioned that the subjective standards of quality set by the radiologists would be important in evaluating the effectiveness of the quality assurance program.

Proposed § 1000.55(c)(6) stresses the importance for planning and evaluation purposes of keeping accurate records. This was the quality administration procedure most often mentioned in the responses to the advance notice. Such records are essential for guaranteeing that necessary monitoring and maintenance have been performed. They are basic for making effective use of the warranty provisions on X-ray equipment and the services of the manufacturer's representatives, as an aid in future equipment selection, and for planning the replacement schedules for X-ray equipment. They are also necessary for adjusting the quality assurance program so that the greatest effort is placed in the area of greatest need. Finally, records are useful to support the need for a quality assurance program.

Proposed § 1000.55(c)(7) stresses the need for all staff members to be informed of their responsibilities in the facility quality assurance program. The Commissioner has found that ready reference to the necessary information is best guaranteed by an easily available program manual. The contents of a manual would of course depend on the size and complexity of the facility, e.g., individual practitioners might be able to rely heavily on standard protocols developed by government or private bodies while larger, more specialized facilities might need to develop their own. Even in the second case, quality assurance publications prepared by government and private bodies would provide useful instructions on individual procedures and might well be listed in response to proposed § 1000.55(c)(7)(iii) and (vi).

Proposed § 1000.55(c)(8) emphasizes the importance of well-trained personnel. Many comments were in general agreement that training was basic to the success of a quality assurance program. Some suggested that training could also be used to encourage implementation of quality assurance programs. As already noted, the lack of trained personnel was also cited as a practical barrier to implementing quality assurance programs, but government and private groups are taking steps to make quality assurance training available. The Bureau, through its Diagnostic Radiology Quality Assurance Catalog, is seeking to disseminate information on these training programs.

Proposed § 1000.55(c)(9) emphasizes the importance of establishing a quality assurance committee with representation from all segments of the medical staff. Representative committees have proved successful in the institutions working with radioactive materials under a Nuclear Regulatory Commission license, in medical facilities dealing with problems such as planning for major disasters, and in at least one diagnostic radiology quality assurance program. The Commissioner believes that such committees would be useful also in the diagnostic radiology area for the purposes listed in proposed § 1000.55(c)(9) and to solve other administrative problems as they arise. The Commissioner realizes that committees would be feasible only for larger facilities, not for individual practitioners' offices.

Proposed § 1000.55(c)(10) stresses that periodic review and update of the quality assurance program are necessary in all facilities if the program is to continue to provide the maximum possible benefits.

REFERENCES

(1) Trout, E. D., G. Jacobsen, R. T. Moore, and E. P. Shoup, "Analysis of the Rejection Rate of Chest Radiographs Obtained During the Coal Mine Black Lung Program," *Radiology*, 109:25-27, 1973.

(2) Beideman, R. W., O. N. Johnson, and R. W. Alcox, "A Study to Develop a Rating System and Evaluate Dental Radiographs Submitted to a Third Party Carrier," *Journal of the American Dental Association*, 93:1010-1013, 1976.

(3) Hall, C. L., "Economic Analysis of a Quality Control Program," to be published

in *Application of Optical Instrumentation in Medicine, VI, Proceedings of the Society of Photo-Optical Instrumentation Engineers,* 127, 1977.

(4) Brown, M. R., "Preventive Maintenance Reduces X-Ray Equipment Costs," *Dimensions in Health Service,* 51:3, 1974.

(5) Starchman, D. E., R. G. Johnson, and W. J. Howland, "Linearity of Exposure with Indicated Time and Current for Diagnostic Radiography Units," *Radiology,* 122:489-492, 1977.

(6) Starchman, D. E., R. G. Johnson, D. L. Hykes, and W. J. Howland, "The Role of kVp Accuracy of Diagnostic X-Ray Units and Other Performance Parameters in Quality Assurance," *Application of Optical Instrumentation in Medicine, V, Proceedings of the Society of Photo-Optical Instrumentation Engineers,* 96:31-36, 1976.

(7) Morgan, R. H. and E. F. Gehret, Jr., "Gonad Exposure in Medical Radiography: A Handbook of Scatter/Primary Exposure Ratios," BRH/DMRE Contract Report: PH 86-68-63, Public Health Service, U.S. Department of Health, Education, and Welfare, May 1971.

(8) Bunge, R. E., R. E. Gross, J. J. Vucich, and M. H. Barnett, "The Need for Quality Assurance in Diagnostic Radiography," presented at the *Midyear Symposium of the Health Physics Society,* 1976.

(9) Vucich, J. J., "Quality Assurance: A Fundamental Whose Time Has Come," *Application of Optical Instrumentation in Medicine, IV, Proceedings of the Society of Photo-Optical Instrumentation Engineers,* 70:138-144, 1975.

(10) Goldman, L. and J. J. Vucich, "Automatic Processing QA: Impact on a Radiology Department," *Radiology,* 125:591-595, 1977.

(11) Environmental Impact Analysis Report for the Recommendation for Diagnostic Radiology Quality Assurance Programs, 1977.

(12) Barnes, G. T., R. E. Nelson, and D. M. Whitten, "A Comprehensive Quality Assurance Program: A Report of Four Years Experience at the University of Alabama in Birmingham," *Application of Optical Instrumentation in Medicine, V, Proceedings of the Society of Photo-Optical Instrumentation Engineers,* 96:19-23, 1976.

(13) Randall, M. G. and B. Horn, "A Systems Approach to Acceptance Testing of Diagnostic X-Ray Equipment," to be published in *Application of Optical Instrumentation in Medicine, VI, Proceedings of the Society of Photo-Optical Instrumentation Engineers,* 127, 1977.

(14) Stone, T., "Radiological Systems Acquisition Procedures," to be published in *Application of Optical Instrumentation in Medicine, VI, Proceedings of the Society of Photo-Optical Instrumentation Engineers,* 127, 1977.

The Food and Drug Administration has determined that this document does not contain an agency action covered by 21 CFR 25.1(b), and consideration by the agency of the need for preparing an environmental impact statement is not required. Pertinent background data and information on the recommendation proposed herein are on file in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 356, 82 Stat. 1174-1175 (42 U.S.C. 263d)) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 1000 be amended by adding new § 1000.55 to read as follows:

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§ 1000.55

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[FR Doc. 78-11532 Filed 4-27-78; 8:45 am]

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†10.3 Final Regulation—December 11, 1979

- 44 FR 71728 -

PART 1000—GENERAL

[Docket No. 76N-0145]

Quality Assurance Programs for Diagnostic Radiology Facilities

AGENCY: Food and Drug Administration.

ACTION: Final Recommendation.

SUMMARY: The agency is issuing a recommendation that encourages voluntary establishment of quality assurance programs by all diagnostic radiology facilities. The recommendation suggests some aspects of the programs, but recognizes that the programs will vary with each facility's size, type, and needs. The agency wants to minimize unnecessary public exposure to electronic product radiation.

EFFECTIVE DATE: December 11, 1979.

FOR FURTHER INFORMATION CONTACT:

Charles P. Froom, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of April 28, 1978 (43 FR 18207), the Food and Drug Administration (FDA) proposed to add new § 1000.55 (21 CFR 1000.55) to Subpart C—Radiation Protection Recommendations, Part 1000 of Chapter I of Title 21 of the Code of Federal Regulations. New § 1000.55 would recommend that health practitioners and others responsible for operating diagnostic radiology facilities establish quality assurance programs. Seven professional organizations, 14 representatives of government agencies (from 9 agencies), 1 processing chemicals manufacturer, 3 medical facilities, and 33 individual dentists, engineers, physicists, radiologists, technologists, and state employees submitted substantive comments. These comments and the agency's response to them follow:

Comments on the Approach Taken

1. Seven comments endorsed the voluntary approach for encouraging the implementation of quality assurance programs; three said the recommendation would eventually have to be made a regulation to be effective. One of these three suggested that, as an intermediate step, the recommendation be tested in Federal hospitals. Several other comments interpreted the publication as a proposed regulation instead of a proposed recommendation (an error that two other comments predicted would occur more generally). These comments indicated that the recommendation would require that all facilities monitor all of the parameters listed, establish all of the levels of responsibility mentioned, keep extensive records to satisfy some agency outside the facility, include in their manual all items suggested, and comply with other requirements. Some apparently also interpreted the recommendation as saying that facilities already consistently producing good quality images with minimum patient exposure would have to add the recommended actions to their existing program. They feared this would add costs to the facility without giving added benefits.

FDA emphasizes that establishing quality assurance programs in accordance with the recommendation is indeed voluntary. In § 1000.55(a) and in the definition of "diagnostic radiology facility" in §1000.55(b), the agency attempted to make clear its belief that quality assurance programs would be beneficial in all types of diagnostic radiology facilities. In § 1000.55(c), the recommendation suggests 10 elements for this program. Proposed § 1000.55(a) stated, however, that the extent to which each element of a quality assurance program is implemented in a particular facility would be determined by that facility after its analysis of its objectives and resources. Especially for some small facilities, the cost of implementing every suggestion might exceed the need and benefit. However, the agency believes that the savings resulting from implementing an appropriate program would, in most cases, offset the cost of the actions. Each facility is, therefore, encouraged to implement only those recommendations it believes would lead to benefits in improved image quality, reduced radiation exposure, and/or reduced costs sufficient to compensate for the costs of the action.

To highlight the flexibility enjoyed by the facility with this voluntary approach, the following changes were made in the introductory section: (1) The second sentence of § 1000.55(a) was made the second sentence of § 1000.55(c). (2) A third sentence was added to § 1000.55(c) to emphasize further the flexibility given to each facility. Some additional changes were made in the wording of the specific elements of § 1000.55(c) to emphasize that the program is voluntary. These changes are discussed in response to the comments on the specific paragraphs of the recommendations.

Comments on the Data

Several comments addressed the studies cited to support the need for and value of quality assurance programs.

2. One comment supplied information on the changes made in the pneumoconiosis compensation program since it was studied for the Department of Health, Education, and Welfare's National Institute of Occupational Safety and Health (NIOSH) by the late Dr. Dale Trout. Before participating in the current pneumoconiosis program, facilities must submit to NIOSH sample chest radiographs and a radiograph of a test object developed by Trout. These radiographs must be considered of acceptable quality for the proper classification of pneumoconiosis before NIOSH approves a facility for participation. The reader system has also been changed. C readers are no longer used, and the B readers have been expanded from members of the three major medical centers mentioned in the proposed recommendation to all physicians who have passed an examination administered by NIOSH.

As noted in the proposed recommendation, Trout found in his study that 44 percent of the certified facilities examined had 10 percent or more of their radiographs rejected by the B or the C readers, which were then being used. The total rejection rate for all facilities was 3 percent. As a result of NIOSH's efforts, in the second round of examinations only approximately 9 percent of the facilities had a rejection rate of over 10 percent. During the January 1 to September 30, 1976 period, the average rejection rate was only 0.6 percent. For the third round of examinations, NIOSH has stated that all X-ray facilities that have a rejection rate of 5 percent or more will have to be reapproved.

Because the improvement is attributed by NIOSH to their "* * * quality control requirements for equipment and expert reading for a radiographic quality by B readers," comparison of the new data with the Trout results gives a "before" and "after" picture for judging the impact of quality assurance. FDA commends NIOSH and the participating facilities for their outstanding efforts in reducing unnecessary patient exposure.

3. Another comment questioned the cost savings that several studies attributed to quality assurance programs, on the ground that facilities that already had successful programs would not be able to achieve additional savings of the magnitude seen in these studies. Referring to facilities with successful quality assurance programs, this comment argues further that "additional regulations imposed on an effective quality assurance program would in fact raise cost."

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The savings found in all the various studies were determined by comparing conditions before implementation of a quality assurance program with conditions thereafter. The FDA estimate of the cost and exposure reduction impact of nationwide quality assurance programs was likewise based on before and after conditions. Quality assurance actions implemented by facilities, with or without effective quality assurance programs already in place, will indeed involve some cost. The crucial question the facility must ask itself is, whether these actions provide sufficient benefits in terms of money savings, reduced radiation exposure, or improved image quality to compensate for the costs. If the benefits outweigh the costs, then FDA encourages the facility to undertake the quality assurance actions. The facilities involved in the studies referred to by the comment found that the money savings alone more than paid for the costs of the quality assurance program. Thus, the benefits exceeded the costs even without taking into account any benefits from reduced exposure to radiation and from improved image quality.

Facilities that now have little or no quality assurance activity are likely to obtain the largest savings from establishing a quality assurance program. Facilities that have established quality assurance programs are probably doing many of the things suggested by the recommendation. The latter may achieve some additional benefits by incorporating the remaining suggestions into their program, but if additional benefits do not seem likely, then there would be no reason to increase their quality assurance efforts in the ways suggested. At any rate, the agency reemphasizes that implementation of the program is voluntary. Contrary to the comment's suggestion, no rules are being "imposed" and no "regulations" are involved.

4. Another comment criticized the use of the Nationwide Evaluation of X-Ray Trends (NEXT) data. The preamble to the proposed recommendation noted that the results of the NEXT study indicate that a "standard patient" would have received widely different exposures for the same examination in different facilities or even with different machines within the same facility. This range of exposure is as much a factor of 100 with some of the 12 examinations considered by NEXT and at least a factor of 10 for any of the examinations. FDA suggested in the preamble to the proposal that unnecessary radiation exposure may be caused by exposure variation that could be eliminated by quality assurance. The comment argued, however, that the differences among facilities are "chiefly due to the wide variety of image receptor sensitivities and peak kilovoltages employed."

The original analysis of the NEXT data did not divide the measured exposure data into groups based on the values of the various technical factors. However, the values of certain technique factors, among them peak kilovoltage (kVp), were collected. An analysis of the effect of different techniques has been done (Bunge, et al., 1976, Midyear Symposium of the Health Physics Society), and it has been found that, even with kVp and half-value layer (HVL) limited to a narrow range, there was still a large variation in the output of the machines. For example, with a kVp range of 78 to 82 and HVL range of 2.3 to 2.7 mm of Al, the output in milliroentgens per milliampere-seconds (mR/mAs) at 12 inches varied from less than 5 to 100. Choice of kVp by the practitioner thus does not explain the wide variation in exposures from facility to facility.

FDA has concluded that machine malfunction leading to the actual kVp and mAs values deviating from the machine settings is a major contributor to the large variation in the output values. (In the NEXT system, the kVp and mAs values are recorded from the machine settings, in contrast to the exposure values, which are measured, and the HVL values, which are calculated from exposure measurements.) For example, if a practitioner chooses to set a machine at 80 kVp, this does not mean that this is the kVp actually produced. Machine malfunction would be a problem that could be minimized by an effective quality assurance program.

The other factor mentioned by the comment, "the wide variety of image receptor sensitivities," has been studied in the last 2 years with the use of an image receptor module add-on to the main NEXT system. When a sufficient number of surveys was completed, multiple regression analysis of the P/A chest projection data was carried out using the factors of kVp, HVL, relative speed of the image receptor, grid, type of processing, and mAs. It was found that these factors could account for only 50 percent of the exposure variation (Showalter, et al., *Proceedings of the Society of Photo-Optical Instrumentation Engineers,* 127:136-139). Thus, the exposure variation cannot be explained solely on the basis of the practitioner's choice of technique factor, image receptor, etc. This analysis will be continued with more examinations as sufficient data become available. At present, it supports the conclusion drawn in the preamble of the proposed recommendation, that part of the exposure variation seen by NEXT represents unnecessary patient exposure due to equipment malfunction that might be reduced or eliminated by quality assurance programs.

5. The comment referred to in paragraph 4 argued further that the mR/mAs variation was due to the method used in calculating the HVL from the NEXT measurements, not machine malfunction. The comment said the method resulted in erroneous HVL values, which accounted for the wide variation in mR/mAs found with machines with similar HVL's.

The NEXT method, which is designed to allow a rapid survey to minimize disruption of facility routine, cal culates HVL using a linear least-squares fit to three exposure measurements. FDA has evaluated the potential error in HVL's however, and found that for the kVp and HVL range reported, the maximum value would not exceed 12 percent. FDA does not believe that the small potential errors in the NEXT HVL measurements can account for the wide range in output found in machines with similar kVp and HVL values. Thus, the agency still concludes that a significant part of the mR/mAs variation is due to deviation of the actual kVp and mAs values from the machine settings. Again, this is a problem that can be minimized with a quality assurance program. The agency concludes that the comment does not invalidate the use of the NEXT data for this recommendation.

6. The comment discussed in paragraphs 4 and 5 also argued that the practitioner should be free to choose whatever techniques lead to radiographs that meet the practitioner's requirements.

This comment indicates a philosophical difference with FDA. FDA agrees that the practitioner must have the latitude to select equipment and techniques that meet the practitioner's special imaging requirements. There is, however, generally a range of exposures that will produce radiographs with roughly the same quality. FDA believes that practitioners should be encouraged to choose those techniques that give the least radiation exposure. Secondly, even when a set of technique factors is shown to be appropriate for a specific imaging

task, quality assurance programs can ensure that the practitioner's equipment is actually delivering the technique values the practitioner has selected. This helps avoid the possibility that the practitioner or the practitioner's operator may repeatedly have to change the technique factors (usually toward higher exposures) due to the decreasing ability to get a satisfactory image with the old values.

7. Another comment criticized the NIOSH and Pennsylvania Blue Shield studies because, in its view, the "vast majority" of problems revealed by these studies "were due to human error" and, therefore, would be unaffected by an equipment quality assurance program.

In the NIOSH study, Trout simply listed the problems he found, without indicating their relative magnitudes. Some were probably due to human error and some to equipment malfunction, but there was no basis for concluding that either category was responsible for a "vast majority" of the problems. However, the later data from this study indicate that, regardless of the source of the problems, the quality assurance program was effective in solving many of the problems identified.

The Blue Shield study did provide a breakdown of the reasons for judging the submitted radiographs to be unsatisfactory. A little over 30 percent of the submitted radiographs were rejected for reasons that were probably due to human error. However, another approximately 20 percent of the submitted radiographs were rejected for reasons that were probably due to equipment malfunction. Once again, equipment malfunction was proven not to be an insignificant problem.

FDA agrees that "people errors" lead to unsatisfactory radiographs and unnecessary patient exposure. But this does not mean that the equipment problems can be ignored. FDA has launched or is developing several programs in the "people" areas, but the agency is also supporting quality assurance programs to deal with equipment problems. Quality assurance actions may also help solve some of the "people" problems. For example, evaluation measures such as retake analysis can help identify operator performance problems. Identification is, of course, the first step in solving the problem.

8. The comment referred to in paragraph 7 also criticized the NIOSH and Blue Shield studies as not reflecting the general practice of radiology because they are limited only to pneumoconiosis and dental examinations.

FDA did not present the studies as representative of the total field, but only as an indication of problems in certain specialties. A study by a major film company of more than 150 general radiographic facilities was presented as evidence that the problems found with pneumoconiosis and dental examinations might be present in all types of facilities (Reference 3 in the April 28, 1978 proposal). This study found an average retake rate of 9 percent and an average rejection rate of 13 percent in facilities without quality assurance programs. (The difference between the 9 and 13 percent is partly due to blank films and is also probably partly due to radiographs that were not repeated because other views gave adequate information.) When the facilities established quality assurance programs, they were able to reduce their average rejection rate to 7 percent.

9. The same comment criticized the use of the film company study by noting that the retake rate of 9 percent of the radiographs due to unsatisfactory quality was close to twice that found in previous studies. The comment suggested that the lower retake rate was more representative of national experience than the 9 percent rate.

This assertion is not well founded. Comprehensive studies have not been done. However, the film company study, which examined more than 150 facilities, shows that many hospitals have higher rates. In contrast, the studies relied on in the comment in most cases included only 1 or 2 facilities, a slim basis on which to estimate representative conditions for the nation. In addition, the authors of at least two of the studies cited by the comment indicated their retake rates were probably underestimated (perhaps by as much as 100 percent in one case) due to various factors including lack of technologist cooperation.

10. The same comment also criticized the agency's estimate in its environmental impact analysis report (Reference 11 in the proposal) of the dose savings impact of quality assurance programs in terms of a total national figure (209,000 to 333,000 rems of active bone marrow dose or 195,000 to 330,000 rems of whole body dose). The comment suggested instead that it would be more accurate simply to state it in terms of the percentage of per capita dose saved.

FDA believes this is simply a difference in philosophy. Physicians, such as the one who commented, treat individual patients, and the agency recognizes that per capita dose might have more meaning to them. As an agency with public health responsibilities, however, FDA must look at the impact on the genetic pool and cost of medical care for the entire population. Thus, the total nationwide savings has more meaning to the agency. It should also be noted that other groups concerned with population exposure, such as the Advisory Committee on the Biological Effects of Ionizing Radiations of the National Academy of Sciences and the United Nations Scientific Committee on the Effects of Atomic Radiation also report dose figures in terms of population dose rather than individual dose. Further, although the savings can be calculated on a per capita basis, the actual dose savings to an individual who did not have to undergo a repeated examination is far greater than the per capita savings, which is only an average figure. Thus, in this particular case the use of per capita dose savings is somewhat misleading even if the concern is with the individual rather than the entire population.

11. In another criticism of the supporting references, the same comment questioned the figure, $37,000 per 300,000 radiographs, for the cost savings due to quality assurance at the University of Alabama at Birmingham (Reference 12 in the proposal). The comment noted that the savings reported were $27,000 per 300,000 radiographs.

The $27,000 figure represented the savings using the discount prices for supplies purchased by the University of Alabama. The $37,000 figure was obtained by using the retail prices. Because discounts vary from facility to facility, the agency believes that retail prices should be used for a fair comparison. Using retail prices, the University of Alabama staff reported an average annual savings in supply costs of $67,566 after quality assurance was initiated. From this the FDA staff subtracted the reported annual quality assurance labor costs of $27,625, the estimated $1,500 a year for supplies for the quality assurance program, and $1,500 for the prorated cost of the quality assurance equipment to obtain an annual savings of approximately $37,000. Because the annual workload at the University of Alabama is approximately 300,000 radiographs, the savings were expressed as $37,000 per 300,000 radiographs.

12. The comment further criticized the agency's use of the Alabama data because, according to the comment, the authors of the study stated that had their department been better organized at the outset, such large savings as they report would not have been possible.

The comment's concern is apparently based on a narrower definition of

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quality assurance than that used by FDA. FDA believes that quality assurance is not limited to taking physical measurements or repairing equipment but is fundamentally a matter of good departmental management. This is one reason why the recommendation is primarily concerned with administration. If implementation of a quality assurance program stimulates or permits an improvement in the general organization of the department (as apparently occurred at the University of Alabama), then the savings from that improvement in organization should be credited to the quality assurance program. This belief is supported by the Alabama authors in their statement that: "The abrupt difference between the 1971-2 and 1972-3 fiscal years is attributed to the implementation of the main aspects of the quality assurance program."

Comments on the Paragraphs of the Recommendation

Many comments focused on one or more of the paragraphs of the proposed recommendation. For each of these paragraphs, the comments are presented, and FDA's reply to them is given.

Applicability

13. The comments addressing § 1000.55(a) chiefly concerned the application of the recommendation to small facilities. Two comments stressed that small facilities should be included. In contrast, one comment said that the major emphasis should be put on the large facilities because their example would stimulate small facilities to join the quality assurance effort. Six comments said that assistance would be needed by small facilities in implementing these programs. Their suggestions as to the nature of the assistance needed ranged from a request to prescribe a program specifically for small facilities to the establishment of regional quality assurance consulting centers. Finally, three comments said it would be impossible for small facilities to implement a quality assurance program as described in the recommendation. This belief seemed to stem in part at least from interpreting the recommendation as having to be implemented verbatim.

FDA recognizes that quality assurance programs for small facilities would be quite different from those for large facilities. For example, a committee such as that described in § 1000.55(c)(9), would obviously be valuable only for larger facilities. All facilities, small or large, are also encouraged to modify FDA's other general suggestions to meet their specific needs where necessary, although the agency believes that the vast majority of its recommendations are applicable to all facilities.

FDA also recognizes that most of the guidance now available on the details of quality control monitoring and maintenance is designed for large facilities. There is a need for guidance directed specifically to small facilities, especially because they do not have their own physicists and quality assurance technologists who could adapt large facility procedures to fit their needs. FDA has begun to collect information on quality assurance programs already available to small facilities. After this information is collected, additional techniques will be developed as needed, and information on both existing and new techniques will be distributed to the facilities. The comments that made suggestions as to appropriate programs for small facilities will be considered in the projects to provide aid to these facilities. FDA believes that these methods of providing assistance to small facilities should be tried before the concept of regional quality assurance consulting centers is considered further because of the expected costs of such centers.

To emphasize that FDA does not expect small facilities to duplicate the programs of large facilities, a sentence has been added at the end of § 100C.55(b)(3), the definition of a quality assurance program, specifically recognizing that any program will vary with the size and type of facility as well as other criteria.

Responsibility

14. A number of comments addressed § 1000.55(c)(1) on the assignment of responsibility for the quality assurance program and of the duties within that program.

Most of the comments addressed the suggested roles for the various segments of the staff, especially the relative roles of the practitioner in charge and of the technologists. Two comments supported the statement that the primary responsibility for the quality assurance program belonged to the medical practitioner in charge of the facility. A third comment implicitly agreed when it criticized the recommendation as not recognizing the importance of the trained radiologist in achieving the goal of reducing unnecessary radiation exposure. In contrast, three other comments argued that the recommendation should give more emphasis to the importance of the staff members involved either with production of images or with maintenance of the equipment. One of these comments specifically criticized § 1000.55(c)(1)(iii) for emphasizing physicists, engineers, and radiologists to the exclusion of staff technologists. A third position was taken by a comment that opposed the entire recommendation because too much emphasis was put on monitoring by technologists rather than on preventive and corrective maintenance by trained personnel. Another comment suggested that the role of the consultants to the facility should be spelled out in more detail. In the proposed § 1000.55(c)(1)(v), it was merely suggested that in some cases it would be of value to assign certain responsibilities to consultants.

In contrast to those comments that argued for increased responsibility for one or another segment of the staff, a response from a professional organization representing a nonradiologist specialty area that makes extensive use of x-ray systems indicated that the practitioners in that area were ready to yield primary if not total responsibility for the quality assurance program to "professionals trained in radiation safety and diagnostic radiology."

Finally, two comments said § 1000.55(c)(1) should be rewritten, though only one included specific suggestions. The latter comment suggested that the responsibilities should be described to fit a program for small facilities, with the roles for specialized personnel as alternatives available to large facilities. This comment voiced concern that small facilities, on viewing the suggestion that responsibilities be assigned to personnel they could not afford, would assume that they could not conduct a quality assurance program.

FDA emphasizes its belief that there are two fundamental areas of quality assurance responsibility in facilities of all sizes, from the individual practitioner's office to the largest medical facility. First, FDA firmly believes that the owner of the equipment, or the practitioner in charge, if different from the owner, must have primary responsibility for the quality assurance program even as that individual has primary responsibility for all other aspects of the facility's activities. This is true whether the owner or practitioner in charge is a radiologist, dentist, cardiologist, or any other specialist. The owner or practitioner in charge may, especially in large facilities, delegate part or all of his or her responsibility to other staff members, but this does not relieve that individual of final responsibility. Furthermore, free and open communication between the practitioner and his or her staff is essential to the quality assurance program. The owner or practitioner in charge cannot

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simply set up the program and then forget it if the program is to achieve maximum success.

Second, FDA recognizes that the staff technologists will play a major role in the execution of the program. In a small facility, staff technologists may often be responsible for all the monitoring and maintenance performed by the facility and may also be responsible for recommending when outside help should be called in for more complex monitoring and maintenance. In a larger facility, staff physicists, quality assurance technologists, service engineers, or supervisory technologists may assume much of the quality assurance monitoring and maintenance responsibility, but the staff technologists will always have the important role of bringing possible problems to the attention of the specialized personnel. This alerting of the specialized personnel makes possible the prompt corrective action that is essential to the quality assurance program.

FDA agrees with the comments that noted that § 1000.55(c)(1)(iii) as proposed did not properly recognize the importance of the staff technologists and maintenance personnel. Therefore, this section has been revised to remedy this deficiency. Section 1000.55(c)(1)(iv) has also been revised to answer the concern of the comment that stated that small facilities would be discouraged by the listing of personnel they could not afford.

Although the suggestions of the comment concerning consultant duties were valuable, FDA has decided not to incorporate them into the recommendation. If more details on consultant duties were included, the duties of other quality assurance personnel should be described in more detail also. In view of the wide variety of diagnostic radiology facilities throughout the country, FDA does not believe that such a detailed description would be appropriate for the recommendation. However, the possibility of providing more detailed suggestions in future technical publications is being considered.

Purchase Specifications

15. One comment noted that one of the greatest problems of a quality assurance program is that manufacturers may simply state that their equipment will not perform within a hospital's specifications.

Section 1000.55(c)(2) recognizes that, in developing purchase specifications, the state-of-the-art should be considered and the need for a specification balanced against the cost of meeting it. If a reasonable set of purchase specifications is developed, then the problem described by the comment should disappear. The facility would deal only with vendors who are willing to meet the specifications and agree to acceptance testing to show that they are meeting the specifications.

16. Another comment on proposed § 1000.55(c)(2) warned that the radiology staff often is not consulted on the purchase of new equipment, or their recommendations are overruled for reasons of finance or convenience.

FDA hopes that the quality assurance program will create channels of communication, such as the suggested quality assurance committee, that will allow the medical and administrative staffs to reach satisfactory compromises on purchase specifications for new equipment.

17. A third comment commended the mention of the alternative of stating the specifications in terms of functional requirements. It also suggested that the availability of experienced service personnel be taken into account in writing purchase specifications.

FDA agrees with this suggestion and has inserted a sentence in § 1000.55(c)(2) to emphasize this point.

18. The same comment also expressed concern about the suggestion that acceptance of the equipment be withheld until the necessary corrections have been made by the vendor. The comment feared that a "self-appointed expert" could break the vendor by being too unreasonable.

The vendor, of course, is entitled to assure himself or herself that the specifications and channels of acceptance are not ambiguous or dependent upon the whim of members of the facility staff. Conversely, if the vendor agrees to meet certain specifications, it is reasonable to require the vendor to meet them. Withholding payment until corrections are made is obviously a powerful weapon, and FDA believes this suggestion should remain in the recommendation. It is, of course, the facility's decision whether to accept this suggestion.

19. Two comments indicated some confusion about the relationship of the purchase specifications and acceptance testing suggested for the quality assurance programs and the requirements of FDA's diagnostic x-ray equipment performance standard (21 CFR 1020.30 through 1020.32). Both comments focused on the report in the preamble to the proposed recommendation from one of the persons commenting on the May 7, 1976 notice of intent to propose the recommendations (41 FR 18863). This individual had tested 50 new rooms of equipment after the vendor had completed installation and adjustment. Not one of the rooms met the purchase specifications. One of the comments on the April 28, 1978 proposal suggested that the vendor be reported for failure to comply with FDA's diagnostic x-ray equipment performance standard, while the other suggested that this was evidence that the performance standard had failed in its mission to remedy problems of improperly performing x-ray equipment.

FDA advises that the purchase specifications suggested as part of a facility's quality assurance program are not synonymous with the requirements of the diagnostic x-ray equipment performance standard. The purchase specifications would be developed by the facility itself based upon its needs. They would most likely address parameters in addition to those minimum requirements covered by the performance standard, which is concerned with radiation safety. Even when the purchase specifications refer to parameters discussed by the performance standard, the facility might decide to put more stringent requirements on the vendor than do the regulations. Thus, the failure of a vendor to meet purchase specifications, as in the case referred to, may have little or no bearing on the question of the value of the performance standard. The incident does underline, however, the importance of not only establishing purchase specifications but of carrying out acceptance testing to see whether they are met.

Monitoring

20. One comment on proposed § 1000.55(c)(3) differed with FDA's approach by arguing that monitoring had been overemphasized greatly. It argued that it is futile to monitor the system if quality radiographs are being produced and that it is also futile to monitor if the system is failing because the failure will be obvious.

FDA disagrees that it is futile to monitor the x-ray system under either of these conditions. If the system is producing satisfactory radiographs, monitoring may still allow detection of problems that exist but have not yet grown to the point where they seriously affect image quality. Thus, if the monitoring is followed by corrective maintenance, problems can be eliminated before they adversely affect patient care. FDA does agree that, if monitoring of a particular parameter does not reveal any change over a period of time, then it would be appropriate to reevaluate the monitoring program for that parameter.

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Similarly, FDA believes that monitoring of parameters after quality control problems appear in the radiograph is of value. The comment suggested that examination of the radiograph in such cases will reveal that a problem exists without the need for monitoring. This is true, but such examination often cannot tell the source of the problem. Monitoring of the parameters and comparing the results with the values from before the problems occurred can be valuable in pinpointing the source of difficulty.

Interestingly, despite its apparent opposition to monitoring tests, the comment stated, "The quality control test can only give information which verifies that a problem does exist or which helps to pinpoint the source of the problem." This statement indicates that the comment recognized these benefits. The comment also correctly noted that testing after a service call can reveal that problems were not resolved because a "manufacturer's service personnel do not always install and maintain x-ray equipment within acceptable standards."

FDA thus has concluded that the importance of monitoring in the quality assurance program should not be deemphasized.

21. The same comment further stated that "testing can only identify a possible problem but will not provide the solution." It also asked, "what good is any test which pinpoints a problem, if there is no one available who is capable of correcting the deficiency?", a question echoed by another comment. The comment also suggested that a major cause of "technologist's apathy" noted in some quality assurance programs was the feeling that quality assurance testing was a waste of time because no one ever did anything when problems were found.

Although FDA does not agree that monitoring should be deemphasized, the agency does agree that maintenance, both preventive and corrective, is important. Preventive maintenance has been shown effective in existing programs (Nelson, et al., *Radiologic Technology*, 49:129–134), and the essential nature of corrective maintenance both to improve equipment performance and to overcome "technologist's apathy" is obvious. Although corrective maintenance has been mentioned in the Evaluation, Records, Manual, and Review elements (§ 1000.55(c) (5), (6), (7), and (10)), further emphasis should be given. Thus, § 1000.55(c)(3) has been retitled "Monitoring and Maintenance", the introduction to this element has been rewritten, and a new subdivision (iv) has been added to provide further comments on maintenance and on the need for trained service personnel.

22. Four comments on the list of possible parameters to be monitored noted that the long list might be discouraging to facilities. The comments suggested various systems for reorganizing the list, such as pointing out the general areas of importance or listing the parameters in their order of importance. Two comments made opposing suggestions: One suggested shortening the list to only key tests; the other suggested general descriptions of the specific quality assurance procedures that should be included.

The agency is concerned that two general problems hamper the reorganization or shortening of the list of parameters. The first is that the field of quality assurance is still rapidly developing, and a consensus on the relative importance of a number of the parameters does not yet exist. In addition, the wide variety of types and sizes of diagnostic radiology facilities and their equipment will probably make it impossible ever to develop a single list of parameters that apply generally to all facilities. Thus, FDA has preferred to develop as comprehensive a list as possible and to encourage the facilities to select the ones to monitor based on what is important to them. FDA has accepted the suggestion of one comment that general areas that probably should be monitored in all programs be listed. This is done in a new § 1000.55(c)(3)(ii). The old § 1000.5(c)(3)(ii) is now § 1000.55(c)(3)(iii). The introduction to § 1000.55(c)(3)(iii) has been rewritten, and the parameter list rearranged to correspond to the areas of new § 1000.55(c)(3)(ii).

23. Two comments referred to the list of parameters to be monitored as reasonable and very important, but other comments made a number of suggestions on adding or deleting parameters.

FDA has added four parameters to the list in response to these suggestions. These are "view box surface conditions," added to § 1000.55(c)(3)(iii)(*d*), "continuity of exposure" and "flatness of cassette" added to § 1000.55(c)(3)(iii)(*f*), and "representative entrance skin exposures" added to § 1000.55(c)(3)(iii) (*b*) and (*f*). In addition, suggestions that mechanical and electrical components undergo visual inspection have been added to new § 1000.55(c)(3)(iv) on maintenance. FDA did not accept suggestions that nominal voltage and latent images in intensifying screens be monitored. The comment did not provide documentation to support the belief that variations in these parameters cause problems, and FDA is unaware of any evidence that they do.

As suggested, FDA has dropped the parameter, "solution compositions" from § 1000.55(c)(3)(iii). It is now generally accepted that pH measurements of the solutions are of little value in quality assurance monitoring and that specific gravity measurements are of value only in determining whether a fresh batch of solution has been correctly mixed (and then only if the proper value is known for comparison). FDA also agrees that other methods of monitoring solution composition require a strong knowledge of chemistry and more effort than is warranted by the results.

The suggestion that focal spot measurement should be dropped until there is a consensus standard for such measurements was not accepted. FDA believes that any of the existing methods are accurate enough for quality assurance purposes as long as the same method is used consistently. FDA also did not agree that "linearity of mA stations" should be dropped. Although this measurement is perhaps covered by the monitoring of the parameters of automatic exposure control devices, it would not be covered with machines lacking these devices.

A suggestion that it was too early to establish quality assurance protocols for computed tomography (CT) systems was not accepted. It is not too early to develop an awareness that quality assurance monitoring is necessary for these devices even though the methods might require more effort. (Most CT manufacturers even provide a test device that can be used to monitor some parameters.)

One comment also suggested dropping daily measurement of fixer temperature, while another suggested that with tomographic units, "thickness of cut plane," "flatness of field," and "exposure angle" could be dropped because these parameters would not change very rapidly. It appears that the disagreement is not so much with these parameters as with the frequency of monitoring. It should be noted that the frequency of monitoring of the parameters has been left to the facility to decide. Thus if the tomographic parameters do not change rapidly, semiannual or annual monitoring of these might be sufficient, while other parameters, such as some of those involved in film processing, might have to be done daily. Similarly, the frequency of fixer temperature

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monitoring could be chosen to correspond to facility needs. Facilities are encouraged to consider revision of the monitoring schedules for the different parameters as part of the evaluation and review elements.

24. Comments also suggested that the parameters "response capability" in proposed § 1000.55(c)(3)(ii)(*e*) and "accuracy of SID indicators" in proposed § 1000.55(c)(3)(ii)(*d*) are not clear.

FDA agrees and, in an effort to solve this problem, has changed these parameter names to "minimum response time," and "accuracy of SFD indicators," respectively. (With the reorganization of the parameter list mentioned above, these parameters are now under § 1000.55(c)(3)(iii)(*b*).)

25. With respect to monitoring parameters, several comments pointed out that work remains to be done on the procedures for monitoring many of them.

Fortunately, efforts are under way in both the private and public sectors to fill these gaps, and FDA will continue to encourage progress in these areas.

†Standards for Image Quality

26. Three comments addressed § 1000.55(c)(4) on setting standards for image quality. Two comments remarked about the difficulty of setting standards for quality in view of the many different opinions of what constitutes adequate quality and whether that quality should be measured or be determined by "the eye of the beholder." One comment urged that, because of this, the paragraph should either be rewritten or deleted. In contrast, a third comment urged that FDA go further by helping the facilities set standards of quality and by conducting frequent inspections to ensure that the standards are met.

FDA believes that some definition of acceptable standards of image quality is essential if quality control monitoring and maintenance is to be effective. The purpose of the monitoring is to detect parameter variations that may cause or are causing image quality problems. Appropriate standards of image quality would serve as a guide to indicate when these variations have become serious enough to require corrective action.

Ideally, if the values of these parameters are kept within certain defined limits, the image quality will be acceptable. If such limits can be agreed upon, they can serve as the standards for image quality. Such objective standards may be emerging with respect to processor performance. FDA realizes, however, that, for most parameters of the x-ray system, the standards of image quality will remain subjective for some time. This is largely because of a lack of consensus among medical practitioners as to what is "good" quality, and in some cases means for measuring the relationship between parameter variation and quality may be lacking.

FDA believes that it is not now possible or desirable to develop uniform nationwide standards. Instead, the practitioners in each facility are encouraged to determine their own standards of image quality based on their training and experience and to relate these standards to system parameter values. FDA has suggested and will suggest in other publications objective standards of image quality as they become known from research and the experience of medical facilities. In the future these objective standards (or those from other sources) may become the national norm. However, even if this should occur, the implementation of these standards would still be on a voluntary basis.

In conclusion, FDA does not agree that changes in § 1000.55(c)(4) are warranted at present.

Evaluation

27. Three comments on § 1000.55(c)(5) said that the importance of reject analysis in evaluating both the total program and the individual technologist's performance should be further emphasized.

Reject analysis is referred to in § 1000.55(c)(5)(ii) as "ongoing studies of the retake rate and the causes of the repeated radiographs." FDA agrees with the comment that the emphasis should be increased to reflect the fact that reject analysis is probably the most useful evaluation method now available. Several sentences have been added to § 1000.55(c)(5)(ii) to emphasize the value of studies of the reject rate and to suggest study characteristics and frequencies.

Records

28. Many comments were received on the recordkeeping recommendations in proposed § 1000.55(c)(6). Several comments urged that FDA emphasize the importance of maintaining records by conducting inspections of them. Others interpreted the recordkeeping suggestions as regulatory requirements and opposed them as being an added burden. One comment took an intermediate position. It recognized that the proposals on recordkeeping were recommendations, but feared that states might adopt them as regulations. This might make the recordkeeping an end in itself rather than a tool for achieving improved performance.

The importance of recordkeeping cannot be overemphasized. FDA is convinced that accurate and complete records are essential for guaranteeing that necessary monitoring and maintenance have been performed, for making effective use of the equipment warranty provisions and the services of manufacturers' representatives, for aiding in future equipment selection, for planning the replacement schedule for x-ray equipment, and for evaluating the quality assurance program so that it can be modified for maximum effectiveness.

The agency recognizes, however, that the extent of the recordkeeping, just as all other aspects of the quality assurance program, should be determined by the facility itself on the basis of what is necessary for support of its program. Because recordkeeping recommendations, like all others, are voluntary, FDA inspections to enforce them would be unauthorized by law and inappropriate.

FDA shares the concern of the comment that suggested recordkeeping might become an end in itself. Obviously the purpose of keeping quality assurance records is not just to record numbers, but to collect data that can be used. These data should be used in the evaluation (§ 1000.55(c)(5)) and review (§ 1000.55(c)(10)) elements to determine whether either the equipment or the quality assurance program itself requires adjustment to ensure effective performance. Furthermore, some problems occur periodically. Therefore, records of successful past corrective actions will help to solve the problems quickly when they recur. Clear records may also be quite useful to the facility in demonstrating the need to change vendors or improve purchase specifications.

In a further response to the comments on recordkeeping, and to clarify FDA's views, § 1000.55(c)(7) has been rewritten. In response to a question raised by one comment, § 1000.55(c)(7)(vii) has also been changed to make it clear that the facility decides how long records are to be kept.

Manual

29. The several comments on § 1000.55(c)(7) generally agreed upon the importance of a manual. One comment, however, said that for its purposes a series of manuals already in use in its agency would be preferable to that suggested in the recommendation. Two other comments made opposing suggestions. One urged that some details, specifically the suggestion for a loose-leaf format, should be deleted, while the other suggested that more details, even a complete sample manual, should be provided, though not necessarily as part of the recommendation.

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Facilities are encouraged to modify the recommendations to meet their own needs. Any facility or agency may use materials of a different type or content to meet the goal of keeping all concerned personnel informed about the quality assurance program and their own quality assurance responsibilities. The introduction to § 1000.55(c)(7) has been rewritten to make this clearer. The "loose-leaf" format suggestion has also been dropped. In response to the request for more detail, other FDA publications, available or planned, will provide details on some of the items suggested for the manual. A sample manual for individual practitioners may result from a project to provide guidance to small facilities, which has recently been initiated by the FDA.

Training

30. Several comments urged that the agency expand proposed § 1000.55(c)(8) both to emphasize the importance of training and to specify further its nature.

FDA does not believe that this recommendation is the place to give detailed descriptions of training requirements because these requirements are likely to change with time. However, the training element has been expanded somewhat to emphasize the need for both initial and continuing education and the value of supervised instruction.

31. Several other comments suggested training programs that FDA might initiate or support.

The agency advises that it will continue its efforts, through the production of training materials and through cooperation with professional organizations and industry, to increase the quality assurance training available.

32. Two comments in reference to § 1000.55(c)(1), asked what is meant by the term "qualified" when referring to personnel who might be assigned quality assurance duties.

Again, FDA does not believe that these recommendations provide the proper forum for a detailed list of qualifications because these might well change with time. However, § 1000.55(c)(1) has been modified by addition of the words "by training or experience" following the word qualified wherever it appears.

33. Another comment related to training said the recommendation did

not recognize the training in radiation protection received by radiologists.

Section 1000.55(c)(1)(ii) states that the practitioner in charge of the facility has primary responsibility for the quality assurance program. If a radiologist is a staff member at the diagnostic radiology facility, that specialist will almost certainly be in charge of the facility. Thus, the recommendation does give recognition to the training received in that specialty. However, FDA does not believe that it can single out any medical specialty as being especially qualified by its general training for quality assurance duties. Although some radiologists have been very active in the quality assurance area and have pioneered in the development of quality assurance programs, FDA's information on training of these specialists indicates that quality assurance techniques and procedures are not routinely made a part of their education or certification examination.

Committee

34. The comments on the suggestion that a quality assurance committee (§ 1000.55(c)(9)) be established at large facilities were mixed. Some comments endorsed the idea and suggested that the membership and duties of the committee be expanded. Other comments, however, expressed fears that such a group might "throttle" or frustrate" the program.

The recommendation to establish a committee resulted from a comment on the May 7, 1976 notice that described the success of a quality assurance committee in a facility as well as from the agency's knowledge of the value of committees in other areas. FDA still believes that a quality assurance committee can be useful in facilitating open and frequent communication among the various groups in a facility and such communication is essential for the quality assurance program. FDA does recognize, however, that, depending upon the attitude of its membership, a committee might act to frustrate the quality assurance program. To help forestall this possibility, changes have been made in § 1000.55(c)(9) to clarify the agency's belief that any quality assurance committee should serve communications and policy-making roles rather than an operational role. The proposed recommendation recognized that small facilities would not find a committee useful. Large facilities also do not need to organize such a committee if it is believed to be unneeded or counterproductive. Also, ll 100.55(c)(9) has been reworded slightly to indicate that the facility may not wish to assign all the suggested responsibilities to the committee. Other wording changes are intended to make clear that representatives of all departments with x-ray equipment should be included, if possible, to ensure maximum communication. Also, changes have been made to indicate that the duties of the committee could be given to an already existing committee, as one comment suggested, rather than a newly established committee. All the groups involved with diagnostic radiology should be represented on that committee.

Comments Suggesting Additional Actions

35. One comment urged that an eleventh quality assurance element—on "patient exposure"—be added to the recommendation. The comment suggested that, just as § 1000.55(c)(4) suggests establishing acceptability limits for variations of image quality parameter values, a patient exposure element could contain acceptability criteria for variation in exposure for different examinations.

FDA's quality assurance activities, including the proposed recommendation, are directed at achieving optimal diagnostic x-ray equipment performance. The agency believes that such performance will lead to reduced patient exposure as well as high image quality and reduced medical costs. A separate patient exposure recommendation would significantly expand the proposed recommendations beyond their intended scope, which is limited to equipment performance. Injection of this new consideration would involve the practitioner's choice of technique factors and raise the complex question of striking the proper balance between patient exposure and image quality. For these reasons, FDA believes that the establishment of standards for patient exposure is too important and too complex to be dealt with merely as one of eleven elements in a quality assurance recommendation directed at equipment performance. Instead, FDA published in the FEDERAL REGISTER of August 17, 1979 (44 FR 48354) a notice of intent requesting information on a number of aspects of the patient exposure problem. This is a preliminary action to possible future recommendations dealing specifically with patient exposure.

Although FDA is not now prepared to recommend standards for patient exposure, the agency does recognize that exposure measurements may be useful in evaluating equipment performance. Thus, as noted above, the "representative entrance skin exposures" has been added to the list of parameters to be considered for monitoring in § 1000.55(3)(iii).

36. Several comments suggested that FDA publish recommendations or regulations in areas other than quality assurance to reduce radiation exposure. These suggestions included limitations on the types of equipment that could be used, film-screen standards, new designs of equipment to provide for easy quality assurance testing, specification of techniques to be used, and certification programs to ensure that the owners and operators of x-ray equipment are adequately trained.

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FDA appreciates these expressions of concern and will consider them in planning future programs. The agency advises that activities in cooperation with professional groups or other agencies are already being planned or are under way in some of these areas, e.g., film-screen standards and certification programs. However, inclusion of recommendations in these added areas as part of the basic quality assurance recommendation would significantly expand this recommendation beyond its intended scope. The agency believes that it is more appropriate to proceed independently in these other areas.

37. One comment suggested that patient exposure reductions could be achieved if the States were encouraged to make more frequent inspections of radiology facilities.

FDA believes that this suggestion is worthy of consideration, but it falls outside the area of a quality assurance recommendation. FDA notes, however, that the Bureau of Radiological Health has undertaken some activities designed to help solve the problem of limited resources for State inspections. The Bureau's efforts have been designed to enable the States to locate facilities with problems so that their resources may be concentrated on them. Two such efforts, the Dental Exposure Normalization Technique (DENT) and the Breast Exposure Nationwide Trends (BENT) programs, have been under way for some time. Both programs use thermoluminescent dosimeter (TLD) mailers to locate facilities with problems. These facilities are then visited by State personnel, who work with them on a voluntary, nonregulatory basis to help solve the problems. Average exposure reductions of 40 percent in dental facilities and 20 percent in mammography facilities have been achieved. Development of similar programs for other types of examinations as well as a program that could be used with facilities doing a number of types of examinations is currently under way.

38. Two comments suggested that the government establish some means of providing quality assurance services, especially for private offices.

The agency's BENT and DENT programs do provide some such services and, as discussed in paragraph 37, this concept is being expanded to other examinations. The time intervals between the BENT and DENT type of contacts, however, are too long for routine quality assurance actions. The option of setting up regional quality assurance centers, equivalent to the Regional Radiological Physics Centers, or programs through professional organizations or private facilities will be kept open. However, owing to the expense of such centers or programs, action will not be taken until the need is more clearly demonstrated.

39. Some comments suggested that FDA enlist the aid of the Joint Commission on Accreditation of Hospitals (JCAH) to encourage the adoption of quality assurance programs. Others as-

serted that the FDA efforts were not needed because the JCAH already "mandated" quality assurance programs.

FDA received a comment from the JCAH, which made clear its interest in quality assurance and radiation protection, and which in general endorsed the FDA approach. It does not appear that FDA suggestions for quality assurance programs for diagnostic radiology facilities either conflict with or duplicate the JCAH efforts to encourage quality assurance in all hospital departments. FDA will continue to coordinate its efforts with those of the JCAH.

40. Three comments mentioned the problem of motivating personnel to initiate and maintain a quality control program.

FDA recognizes that this is perhaps the central problem that must be solved if the quality assurance program is to be successful. The agency believes that the first step in solving this problem is to win the support of the person in charge. Thus, through pilot tests of quality assurance techniques and through its publication program, FDA is attempting to collect and disseminate information on the benefits of quality assurance. FDA believes that this information is essential to convince the practitioner in charge, the facility administrator, and the administrative technologist initially to establish a quality assurance program. FDA is also working to disseminate information (by this recommendation, manuals, etc.) to help the program succeed in the facility once it has been implemented, for such success is the best method of motivation.

41. A conference conducted by the American College of Radiology with FDA support is planned for the fall of 1979. One comment suggested that this conference might be used to write a recommendation to replace the one proposed. The comment suggested further that this could serve as a motivating influence.

In view of the general support for the proposed recommendation, FDA has decided to proceed with publication of this final recommendation. The conference can then be devoted to its original purpose of discussing means to motivate facilities to use the recommendation and other guidance to establish quality assurance programs.

42. One comment suggested that the availability of "sources of information, consultants, and other resources" should be included for the benefit of facilities developing quality assurance programs.

FDA notes that, because such resources would be constantly changing, it would be impractical to include a list in the recommendation. FDA recognizes, however, that it may be difficult for a facility to locate the information, equipment, training, and other items needed for a quality assurance program. To assist in solving this problem, FDA published a Diagnostic Radiology Quality Assurance Catalog in the summer of 1977. The catalog contains information on available quality assurance equipment, services, training materials, and publications. A supplement to the catalog (covering the same types of items) was published in the fall of 1978. More than 12,000 copies of each of these volumes have been distributed, and FDA's Bureau of Radiological Health will continue to provide individual copies free of charge for as long as supplies last.

43. One comment suggested that "any quality control programs should stress conservation of silver and other resources vital to radiology."

FDA notes that quality assurance programs can indirectly conserve resources by reducing retakes and thus by reducing film usage, which in turn would conserve resources such as silver. FDA believes, however, that including direct conservation suggestions would be beyond the scope of this recommendation, which concerns equipment performance. This should not be interpreted as downgrading the value of the important conservation effort.

44. The agency advises that the new references cited in this final recommendation have been added to the administrative record for this matter. These references as well as those cited in the April 28, 1978 proposal are on file in the office of the FDA Hearing Clerk under Docket No. 76N-0145, and

are available for public review in Rm. 4-65, 5600 Fishers Lane, Rockville, MD, between the hours of 9 a.m. and 4 p.m., Monday through Friday.

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Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec, 356, 82 Stat. 1174-1175 (42 U.S.C. 263d)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), 21 CFR Part 1000 is amended in Subpart C by adding new § 1000.55, to read as follows:

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§ 1000.55

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[FR Doc. 79-37739 Filed 12-10-79; 8:45 am]

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†40.—Nuclear Medicine Quality Assurance

†40.1 Notice of Intent—August 17, 1979

- 44 FR 48264 -

[21 CFR Chapter I, Subchapter J]

[Docket No. 79N-0147]

Quality Assurance in Nuclear Medicine; Intent To Propose Voluntary Recommendations

AGENCY: Food and Drug Administration.

ACTION: Advance Notice of Proposed Rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is considering the development of voluntary recommendations for health professionals concerning quality assurance programs for nuclear medicine facilities. So that the recommendations will represent a consensus of expert opinion, they will be developed in cooperation with representatives of professional, public, and private groups and manufacturers that have interest and knowledge in the field. The agency intends to implement the recommendations through educational programs in cooperation with activities of professional organizations and State health agencies. FDA invites public comment on the adoption of such voluntary recommendations and extends to interested individuals and organizations the opportunity to be placed on a distribution list to receive additional relevant material.

DATES: Comments by December 17, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Alex Martin, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: Current FDA involvement in nuclear medicine quality assurance began in the Bureau of Radiological Health (the Bureau) with the establishment of the Quality Control Section in the Bureau's Nuclear Medicine Laboratory in December 1972. In collaboration with the University of Colorado, the Bureau initiated quality assurance workshop programs for the preparation of radiopharmaceutical tests and use of nuclear medicine instrumentation. These activities were pursued in consultation with the Bureau's Medical Radiation Advisory Committee (MRAC), an advisory committee to FDA established under section 222 of the Public Health Service Act (42 U.S.C. 217a). Sponsorship of the workshop series included professional groups such as the Society of Nuclear Medicine and the American Association of Physicists in Medicine. The general workshop topics have included scintillation cameras, radiopharmaceuticals, rectilinear scanners, and in vitro procedures. Workshop manuals and associated technical materials have been published by the Bureau. Copies are on file with the FDA Hearing Clerk and may be requested free of charge from the Bureau at the address above.

As used in this notice and by FDA's Bureau of Radiological Health, the term "quality assurance" includes the planned systematic actions that provide adequate confidence that a diagnostic facility will produce consistently high quality images with minimum patient exposure and at minimum cost. Quality assurance actions include quality control techniques used in the routine physical testing of instruments such as imaging units or counting systems. Active quality assurance programs already exist in a number of nuclear medicine facilities. The Bureau's activities have been designed to make the nuclear medicine community aware of such quality assurance programs, to collect information on current quality assurance efforts, and to test additional techniques for identifying and correcting quality assurance actions in nuclear medicine facilities. The Bureau's experience in quality assurance activities and its consultations with other professional organizations indicate that voluntary, facility-based programs may be appropriate to promote nationwide quality assurance programs.

Accordingly, FDA is considering the development of recommendations for health professionals concerning the utilization of quality assurance procedures in nuclear medicine. These voluntary recommendations, to be based on reports of FDA's Bureau of Radiological Health, will be developed in cooperation with representatives of professional, public, and private groups and manufacturers that have an interest and a knowledge in the field. The recommendations should therefore represent expert opinion upon which individual practitioners and allied health personnel can rely in establishing acceptable quality assurance programs in nuclear medicine. They would be implemented through cooperative educational programs with professional organizations and State health agencies. FDA intends to codify the final recommendations under Title 21 Chapter I, Subchapter J of the Code of Federal Regulations, in a special section established for voluntary recommendations, to make the recommendations readily accessible while ensuring their use and impact. After publication of the final recommendations, the Bureau will continue to publish technical reports giving information and advice on quality control for specific types of instrumentation and procedures. This advance notice is being issued under FDA's policy of early public participation in guideline development activities.

Interested persons are invited to participate in this effort to develop national guidance for quality assurance programs to monitor the performance of equipment and procedures in nuclear medicine by submitting their written data, views, or arguments. Individuals may also request that their names be placed on a distribution list to receive further relevant information. Comments and supporting data would be of particular importance concerning the following:

(1) In what areas of nuclear medicine might quality assurance programs be needed? Please explain the basis for your suggestions.

(2) What benefits (such as improved diagnostic images, maintenance of high image quality, lower cost, fewer instrument failures, reduced patient dose, etc.) should a nuclear medicine facility expect to derive from instrument quality assurance programs? Please document if possible.

(3) What level of effort by the facility (in terms of cost and human effort) is appropriate for maintaining a quality assurance program?

(4) In terms of justifying a quality assurance program for a given nuclear medicine facility, what is the relative importance of direct financial savings compared to maintenance of high image quality and reduction of patient radiation dose?

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(5) What types of programs should be undertaken to promote national adoption of recommended quality assurance procedures in nuclear medicine?

(6) To what extent should manufacturers of nuclear medicine instruments be expected to provide assistance with quality assurance procedures (e.g., by furnishing appropriate phantoms, supplying calibration data, and recommending suitable quality assurance procedures)?

Interested persons may, on or before December 17, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600

Fishers Lane, Rockville, MD 20857, written comments or data on this advance notice of proposed rulemaking. Four copies of all comments should be submitted, except that individuals may submit single copies of comments. The comments should be identified with the Hearing Clerk docket number found in brackets in the heading of this document. All comments received will be considered to the fullest possible extent in formulating any proposed recommendations. Information submitted will be available for public inspection in the office of the Hearing Clerk between 9 a.m. and 4 p.m. Monday through Friday.

This notice is issued under the Public Health Service Act (secs. 301, 310, 311 (42 U.S.C. 241, 242o, and 243)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1).

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[FR Doc. 79-25281 Filed 8-16-79; 8:45 am]

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†50—Devices Used as a Radiation Source in the Photochemotherapy of Psoriasis

†50.1 Notice of Intent—February 8, 1980

- 45 FR 8670 -

[21 CFR Subchapter J]

[Docket No. 79N-0013]

Devices Used as a Radiation Source (in Combination With a Psoralen Drug) in the Photochemotherapy for Psoriasis; Intent To Propose Rules and Develop Recommendations

AGENCY: Food and Drug Administration.

ACTION: Notice of Intent.

SUMMARY: The agency is considering safety performance recommendations for devices used as a radiation source in combination with a psoralen drug in treating psoriasis (PUVA therapy). This notice discusses concepts for improved safety of these devices. Some performance features are related to temperature control, lamp shielding, goggles, and measurement of the radiation level (dosimetry). They are based largely on the radiation safety experience gained from clinical trials in which PUVA therapy has been shown to be effective. The agency intends to examine the concepts described, as well as the comments received, and to propose at a future date safety performance recommendations for the devices. The agency requests further information on this subject and will reexamine its recommendations when significant new information becomes available. Specifically, the agency requests comments on the conceptual recommendations listed in this notice and on general issues related to the safe use of PUVA therapy devices. If it appears that the voluntary approach implemented through safety performance recommendations is not effective as a means of improving the safety of these devices, the agency will consider establishing a mandatory performance standard for PUVA therapy devices.

DATES: Comments by April 8, 1980. Data concerning the safety and effectiveness of PUVA therapy equipment may be submitted at any time.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn E. Conklin, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA), through the Bureau of Radiological Health and under the authority of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.), administers an electronic product radiation control program. This authority provides for the protection of the public health and safety through development and administration of radiation safety performance standards and development of recommendations for controlling electronic product radiation. FDA also has authority under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301-392) regarding safety and effectiveness of drugs and medical devices.

Background

Psoriasis is a disfiguring and often incapacitating skin disease that affects 1 to 3 percent of the world's population. Derivatives of the photosensitizing drug psoralen are now being used along with an ultraviolet-A (UVA) radiation source to treat psoriasis in a therapy known as PUVA (psoralen + UVA). The ingestion of the drug markedly increases the patient's sensitivity to ultraviolet radiation. This effect occurs gradually, reaching a peak 2 to 3 hours after ingesting the drug. The afflicted areas are then exposed to high-intensity UVA radiation, usually from a specifically designed system, although sunlight has been used. Many of the available devices consist of banks of fluorescent lamps mounted inside a cabinet. Usually, the patient stands inside the cabinet for the duration of the treatment. The following discussion focuses on this equipment.

The ultraviolet radiation is nominally limited to the UVA region of the electromagnetic spectrum between 320 and 380 nanometers (nm). Because the shorter wavelength radiation emission is not completely eliminated from the fluorescent lamps, there is patient exposure to radiation of wavelengths shorter than 320 nm and longer than 280 nm, a wavelength range usually called the erythemal or ultraviolet-B (UVB) region of the spectrum. There is also intense visible light at wavelengths greater than 380 nm.

Each wavelength region presents a slightly different potential risk to the patient. As with erythemal radiation from the sun, overexposure to UVB radiation from a PUVA therapy unit could cause eye injury and skin burns (erythema), while repeated overexposure would be associated with skin aging and an increased risk of skin cancer. Laboratory animals treated topically with psoralen derivatives and exposed to UVA radiation developed skin tumors (Ref. 1). Exposure to UVB enhances this effect (Ref. 1). Research has shown that cells grown in tissue culture can be mutated by UVB alone or by the combination of psoralen and UVA. Therefore, the combination of psoralen derivatives and UVA should be considered as a likely carcinogen. It is also possible that psoralen derivatives concentrated in the lens of the eye may, on exposure to UVA radiation, react with lens tissue to form cataracts. The formation of cataracts could also occur after treatment if a patient is exposed to other sources of UVA radiation, such as the sun and most common fluorescent lamps. These sources of UVA radiation could activate psoralen in the lens and cause the formation of cataracts. Chronic exposure to solar UVA alone also has been implicated in cataract induction (Ref. 11).

The use of UVA radiation and orally administered psoralen has been effective in clearing a high percentage of psoriatics, many of whom did not respond to other means of treatment. Also, patients have generally remained free of lesions when given a maintenance therapy consisting of periodic treatment. Numerous patients in various clinical trials have participated; so confidence exists that PUVA therapy can be effective (Refs. 8, 9 and 10). The use of psoralen derivatives and UVA radiation in treating psoriasis represents a medical benefit. However, due to the concerns regarding long term risks of the use of potentially damaging radiation, the situation is as yet unclear whether the benefits of PUVA therapy outweigh the risks (Ref. 7).

No psoralen derivatives have been approved by FDA for treatment of psoriasis. The current use of the drug for treatment of this condition, therefore, is under notices of claimed exemption for investigational new drugs under Part 312 of the regulations (21 CFR Part 312).

Efforts by the Agency and Consultation With Advisory Groups

FDA has reviewed information about PUVA therapy from many sources, including scientific articles, manufacturers' reports, proceedings of agency scientific advisory committees, reports from professional organizations, opinions expressed by interested scientists and physicians, and results of visits to manufacturers of PUVA therapy devices.

FDA visits to six manufacturers of UVA phototherapy devices provided data on the varying extent to which safety features, including those relating to radiation, were considered. For example, one unit provided no lamp shielding. Another unit provided no method for determining radiation dosage. Two units provided no protective eyewear. FDA also discovered that because the lamps' output generally decreases with age, the therapy device needs to be calibrated regularly.

The temperature inside the cabinet version of the device can exceed 120° F (49° C) if no cooling is provided. Even with cooling, the temperature can exceed 100° F (38° C). Protective eyewear must be worn to prevent injury, yet vision is essential for balance and orientation. The lamps must be shielded to prevent breakage and subsequent patient injury in the event of patient collapse. Other mechanical as well as electrical hazards are also a concern.

The Psoriasis and Photobiology Task Forces of the American Academy of Dermatology published in the Academy's journal a joint statement urging caution in the use of PUVA therapy until investigative evaluation could be completed (Ref. 2). The Academy refrained from recommending this treatment until questions about treatment protocols and safety have been answered. Recently, these task forces drafted provisional guidelines for PUVA therapy describing methodology that may be used by physicians with special competence in the diagnosis and treatment of psoriasis and special training and competence in photochemotherapy for treating psoriasis. The draft recommends that PUVA therapy be administered only under the constant supervision of such physicians (Ref. 3).

The Photobiology Committee of the Illuminating Engineering Society, with the endorsement of the Society's Board of Directors, has developed a statement of the risks associated with the use of UVA irradiators being used in treating psoriasis (Ref. 4). This statement has been carefully considered, and elements have been incorporated into this notice.

PUVA therapy devices have been discussed at meetings of four FDA advisory committees. The minutes and transcripts of these meetings are on file with FDA's Hearing Clerk. The General and Plastic Surgery Device Classification Panel of the Bureau of Medical Devices has recommended that the device be classified into class III, which would require premarket approval when implemented. On July 21, 1977 and March 24, 1978, the Panel also suggested that immediate action to eliminate many of the hazards of these devices is needed. The Anti-Infective and Topical Drugs Advisory Committee of the Bureau of Drugs has confirmed the effectiveness of this therapy, but due to concern regarding long-term risks and the lack of data for review regarding long-term use as expressed in meetings in 1977, 1978, and 1979, the Committee is reluctant to confirm its safety. That Committee has stated that extensive information on device performance and long-term risks should be included in the package insert if the drug is approved. The agency has reviewed with the Committee the features on devices proven in clinical use to be effective. They were discussed initially within the Dermatological Subcommittee of the Anti-Infective and Topical Drugs Advisory Committee and were presented to the full Committee at several meetings in 1978. Drug manufacturers, PUVA therapy device manufacturers, and clinicians all participated in the public discussion to develop the list of needed features. The General and Plastic Surgery Device Classification Panel of the Bureau of Medical Devices recommended additional features for patient safety during its meeting on March 24, 1978. The Bureau of Radiological Health's Medical Radiation Advisory Committee, during its meeting of May 9, 1978, supported the need for equipment recommendations to improve the benefits and reduce the risks of therapy. The Technical Electronic Product Radiation Safety Standards Committee, an FDA advisory group established by statute, also endorsed the development of recommendations for equipment safety features, at its meeting of June 1, 1978.

FDA appreciates and encourages the constructive efforts of the industry, professional organizations, advisory committees, and others toward development of standards for safe and effective PUVA therapy devices.

FDA is conducting biological research, evaluating devices, and supporting research on PUVA therapy. No single study is expected to provide all the necessary information. A program of research will be necessary to determine the risk of human health posed by the PUVA therapy. In addition to biological research, the agency will continue to develop methods to measure and evaluate ultraviolet emissions. The Bureau of Radiological Health also encourages users to notify that Bureau (and also the manufacturers of UVA equipment involved) of accidental radiation overexposures. Adverse reactions associated with use of the drug must, of course, be reported to the sponsor and by the sponsor to the agency, as provided in 21 CFR Part 312, while manufacturers of UVA equipment must report accidental radiation occurrences to the Bureau of Radiological Health as provided in 21 CFR 1002.30.

Conceptual Recommendations on the Use and Performance of PUVA Therapy Devices

The following conceptual recommendations are provided for consideration and comment. A brief discussion of the rationale follows the presentation of each concept. These items are expected to form the basis for future proposed recommended standards.

1. *PUVA therapy application.* The Provisional Guidelines on Oral PUVA Therapy (Ref. 3) should be the basis for physician application of PUVA therapy. Manufacturers should include these guidelines in a caution statement for physicians. This statement should accompany the device and should also state that PUVA therapy is considered investigational as a therapy for psoriasis and that the use of psoralen derivatives for this therapy has not been approved by FDA.

2. *Lamp spectral distribution.* The optical radiation emissions from lamps used in these devices should have a spectral distribution as specified in Table I below.

Table I

Wavelength band (nanometers)	Output[1]
<310	<1
>310 to 320	1 to 3
>320 to 330	4 to 8
>330 to 340	11 to 17
>340 to 350	18 to 25
>350 to 360	19 to 28
>360 to 370	15 to 23
>370 to 380	8 to 12
>380 to 390	3 to 7
>390 to 400	1 to 3

[1] As a percent of total irradiance between 320 and 400 nanometers.

Clinical results showing efficacy and short-term safety were obtained using a source having its peak emission at 355 nm and the remainder of the distribution as shown in Table I (Ref. 4).

3. *Exposure uniformity.* The level of UVA radiation within the exposure cavity of the cabinet at any point along the vertical center axis should not be less than 30 percent of the maximum value and, similarly, at any point in any specific horizontal plane should not be less than 20 percent of the maximum value.

Uniformity of exposure of UVA radiation over the body surface is an important aspect of the dosage problem. In some therapy units on the market, the exposure level can vary by more than a factor of two depending on placement of the body in a unit. Exposures of the head and feet areas often are difficult to control because there is less emission at the ends of the fluorescent lamps and the lamps are frequently vertical. By appropriate design of the units, this vertical nonuniformity can be reduced to 30 percent. The horizontal uniformity in UVA level is a function of the number of lamps, the reflectors, reflecting surfaces, and general geometry. It is feasible to design a standup unit in which the patient will receive approximately the same exposure on all sides. This uniformity of better than 20 percent contrasts sharply with the possible al-

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ternative approach of using a single or a few high-intensity lamps.

4. *Dosimetry.* PUVA therapy equipment should incorporate a means for the measurement of the level of UVA radiation, in terms of irradiance (W/cm ^{2}) or radiant exposure (J/cm ^{2}), as defined in 21 CFR 1040.10(b). The error in radiometric measurement should be no more than 20 percent from all sources when calibrated and used in accordance with the procedures and schedules supplied by the manufacturer.

Treatment of psoriatic patients requires prescription of a drug and a radiation dosage. Careful attention has been given in the clinical trials to the measurement of radiation dose, which depends on the number of lamps, the age of each lamp, and the duration of exposure.

The usual practice for therapeutic exposures of radiation is to give an exposure at a level just below that required to produce erythema. This level varies with skin type, previous solar exposure history, and previous treatment history. Depending on the practitioner, the initial exposure may be a judgment based on experience or may be based on trial exposures to small areas. However, owing to the nature of the device, the exposure the physician thinks is being given and the actual exposures delivered to the patient may be considerably different unless adequate care is taken. To err on the low side means the patient has endured a treatment with little benefit, and the total number of treatments and total energy to clear psoriatic conditions may increase. To err on the high side can lead to acute, sunburn-type burns.

Individual physicians should not be required to develop an individual dosimetry and calibration protocol. This should be provided by the manufacturer. The measurements should be representative of the exposure on the patient's body when in place in the PUVA therapy device. The manufacturer should also supply a protocol for avoiding common errors.

The radiometer incorporated in a PUVA device should be designed to avoid or minimize common sources of measurement error. (a) Most detectors respond differently to equal amounts of radiation at different wavelengths. The specific spectral response of the detector and the spectral power distribution of the lamps should be taken into account in the design and calibration of the radiometer. (b) The response of most detectors depends on the angle of the incidence of the radiation on the detector surface and should be taken into account in the design and calibration of the system. (c) The response of the detector is usually dependent on temperature. If the detector is calibrated at one ambient temperature and is used to make measurements at another temperature the calibration may not hold. Because the ambient temperature inside the PUVA unit can be much higher than ordinary room temperature, the procedures should be designed to minimize errors due to the temperature dependence of the detector.

The instructions provided to the user of the PUVA device should specify a schedule for performing the measurements. The instructions should also contain a description of the relationship between lamp output, prescribed radiation exposure, and exposure time.

5. *Timer.* PUVA therapy equipment should incorporate a timer to control the exposure time and to initiate and terminate exposure.

6. *Protection of the eyes.* Protective eyewear (goggles) should be provided with the equipment that will, if worn during treatment, protect the eyes from exposure to ultraviolet radiation. The goggles should, however, transmit enough visible light to allow the patient to see. Visual perception is important for the patient to maintain balance and for general well-being. Instructions should be provided that describe the use of protective eyewear and warn that closing the eyes alone is not sufficient protection. Instructions provided with the equipment should also describe the increased sensitivity to UVA of the eyes and other exposed tissue after the patient ingests psoralen derivatives and should alert the patient to the potential need for protective clothing or eyewear and avoiding ultraviolet radiation from other sources.

Protective eyewear is important because there is a known cataractogenic potential for ultraviolet radiation alone and for UVA radiation when used with psoralen.

7. *Temperature control.* A means should be provided to limit the air temperature within the exposure cavity to 100° F (38° C) or less. Also, there should be warnings in the product literature to physicians to ensure that they monitor patients' reactions.

Cabinet versions of PUVA therapy devices may contain as many as 72 six-foot fluorescent lamps. Manufacturers' statements indicate that, with no forced ventilation to cool the unit, the temperature can exceed 120° F (49° C). The action of the drug plus radiation, the intensity of the output of the lamps, and patient reaction are all uncertain at such elevated temperatures. A recent study of cardiac stress in patients treated for psoriasis in UVA irradiators led to the conclusion that the elevated temperature during a prolonged period of standing relatively immobile could overtax the heart (Ref. 5). Again, as noted by equipment manufacturers, adequate ventilation can reduce the temperature to at least 100° F. The use of forced ventilation to reduce the cabinet temperature will be ineffective unless there is an adequate supply of cooler room air.

8. *Electrical hazards control.* The PUVA therapy devices should have all electrically conductive parts properly grounded or protected from contact under conditions of temperature and humidity encountered during the therapy so that contact with an exposed conductive surface does not place a person at risk (Ref. 6). The devices should include a means for ground fault and circuit overload protection.

For full body treatment, a patient is typically standing while wearing little or no clothing. Elevated temperatures cause perspiration that enhances the possibility of low resistance pathways for current leaks. Even without perspiration, the skin can be exposed to the unit surface, which in turn houses lamps and ballasts that carry large amounts of current. Without proper circuit design and insulation barriers, the potential for electrocution is substantial. If fluids were spilled inside the device, the hazard could be increased. In addition to hazards to the patient, there are potential hazards to the operator and to service personnel. Changing lamps, turning on the device, etc. can be a hazard if the therapy device is grounded improperly and if ground fault protectors are not included in the design. There is also the possibility of a fire breaking out due to circuit overloads, wire shorting, or use of flammable material.

9. *Protection from lamps.* The patient should not be able to come into contact with bare lamps and, in the event of lamp breakage, should not be exposed to the broken glass.

10. *Passage, support, and observation.* The exit from the exposure cavity should open outward, be easily workable from either the inside or the outside, and be safety interlocked to terminate emission of radiation and to stop the timer. Supports that can be grasped by the patient's hands should be provided, and the floor of the exposure cavity should provide traction for bare feet whether wet or dry. Further, the PUVA therapy device should be of sufficient mechanical strength and rigidity to resist abuse, and to withstand the force of a falling person without causing electrical fire or other hazard due to device collapse. An alarm device (panic button) should be provided so the patient can signal an emergency, and there should be an observation window of ultraviolet absorbing material for monitoring the patient's reaction to the treatment.

Although not directly related to radiation safety, the features discussed in the previous paragraph are important because the environment created by the radiation during therapy exposes the patient to certain risks of injury, particularly where a mishap occurs during treatment. For example, even with the restriction on minimum temperature, the interior of the therapy unit can become very hot. The combination of extreme heat and the long periods of standing that may be required as maintenance therapy progresses could cause a patient to faint.

In case of an emergency, a patient should be able to open the therapy unit and exit quickly. To further protect against such emergencies, the door to the therapy unit should open and the lamps should turn off automatically, whenever a patient faints and falls against the door. This safety feature should not only protect against an accidental overexposure, but should also stop the timer so that if the treatment is restarted the exposure time remaining for a full treatment will be known exactly.

Persons or organizations wishing further information on the development of the action program for PUVA therapy devices and their use may phone or write to the contact person whose address appears earlier in this notice.

The following references are on file at the office of the Hearing Clerk, Food and Drug Administration, and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

References

1. Grube, D. D., R. D. Ley, and R. J. M. Fry, "Photosensitizing Effects of 8-Methoxypsoralen on the Skin of Hairless Mice—II. Strain and Spectral Differences for Tumorigenesis," *Photochemistry and Photobiology*, 25, 269–276, 1977.

2. Psoriasis and Photobiology Task Forces, American Academy of Dermatology "PUVA Statement," *Archives of Dermatology*, 113, 1195, September 1977.

3. Epstein, J. and I. Farber, Psoriasis and Photobiology Task Forces, American Academy of Dermatology, "Provisional Guidelines on Oral PUVA Therapy," 1979, *Journal of the American Academy of Dermatology*, 1(2):106–117, August 1979.

4. Photobiology Committee of the Illuminating Engineering Society, "Risks Associated with the use of UV-A Irradiators Being Used in Treating Psoriasis and Other Conditions," *Lighting Design and Application*, March 1979, pp. 56–60 and *Photochemistry and Photobiology*, 30, 199–202, 1979.

5. Rhodes, A., R. Ciagone, and M. Audley, "Cardiovascular Response to PUVA Therapy," *Clinical Research*, 25, 286a, April 1977.

6. American National Standards, Inc., ANS Safe Current Limits for Electrochemical Apparatus, ANSI/AAMI, SCL 12/78, January 19, 1978.

7. R. S. Stern, et al., "Risk of Cutaneous Carcinoma In Patients Treated With Oral Methoxsalen Photochemistry for Psoriasis," *New England Journal of Medicine*, Vol. 300; 809 (April, 1979).

8. Parrish, J. A., T. B. Fitzpatrick, L. Tannenbaum, and M. A. Pathak, "Photochemotherapy of Psoriasis With Oral Methoxsalen and Longwave Ultra-Violet Light," *New England Journal of Medicine*, Vol. 29:1207, 1974.

9. Wolff, K., T. B. Fitzpatrick, J. A. Parrish, et al., "Photochemotherapy for Psoriasis With Orally Administered Methoxsalen," *Archives of Dermatology*, Vol. 112:943, 1976.

10. Melski, J., L. Tannenbaum, J. A. Parrish, T. G., Fitzpatrick, H. L. Bleich, et al., "Oral Methoxsalen Photochemotherapy for the Treatment of Psoriasis; A Cooperative Clinical Trial," *Journal of Investigative Dermatology*, Vol. 68:328, 1977.

11. Zigman, S., "Near UV Light and Cataracts," *Photochemistry and Photobiology*, 26, 437, 1977.

This notice of intent is issued under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (secs. 356 and 358, 82 Stat. 1174–1179 (42 U.S.C. 263d and 263f)); the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301-392); and authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1).

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[FR Doc. 80-3764 Filed 2-7-80; 8:45 am]

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†60.—Radiation Protection X-Ray Intensifying Screens

†60.1 Notice of Intent—June 2, 1978

- 43 FR 24066 -

[21 CFR Subchapter J]

[Docket No. 78N-0074]

X-RAY INTENSIFYING SCREENS

Intent to Develop a Radiation Protection Recommendation

AGENCY: Food and Drug Administration.

ACTION: Advance Notice of Proposed Rulemaking.

SUMMARY: The Commissioner of Food and Drugs announces that the Food and Drug Administration (FDA) is considering development of a radiation protection recommendation advocating the increased use of X-ray intensifying screens made from recently developed phosphor materials. The Commissioner believes that the increased use of these screens in appropriate examinations has the potential for a significant reduction in the radiation exposure experienced by persons undergoing medical radiological examination. Comments on the need for, usefulness, and content of such a recommendation are requested.

DATE: Comments by November 29, 1978.

ADDRESS: Written comments to the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Harvey Rudolph, Bureau of Radiological Health (HFX-460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1960.

SUPPLEMENTARY INFORMATION: Through the Bureau of Radiological Health (BRH) and under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.), FDA conducts and supports research, training, and operational activities to minimize unnecessary exposure of the public to electronic product radiation. In carrying out the purposes of the Radiation Control for Health and Safety Act, the Commissioner is authorized to make such recommendations for the control of electronic product radiation as he considers appropriate (42 U.S.C. 263d). In this capacity and under section 301 of the Public Health Service Act, the Commissioner is considering the development of a voluntary radiation protection recommendation and related information to encourage the use of X-ray intensifying screens made from recently developed phosphor materials which can result in reduced patient exposure. The recommendation would encourage radiographic facilities to use these new screens when appropriate and would provide guidance and suggestions to assist radiographic facilities in adopting these new screens.

This recommendation would be among several that have been or will be proposed by the Commissioner concerning the hazards and control of electronic product radiation or radiation from other sources. Some of these may be made for areas or activities inappropriate for mandatory control. These recommendations are developed in cooperation with national scientific and technical authorities and representatives of professional, public, and private groups that have an interest and knowledge in the field. Therefore, these recommendations will represent a consensus of expert opinion upon which individual practitioners and allied health personnel can rely. These recommendations, which will provide guidance on techniques for reducing unnecessary exposure to electronic product radiation or radiation from other sources, would be implemented through educational programs and cooperative activities with professional organizations and State health agencies. The issuance of this notice is part of the FDA policy of early public participation in recommendation development activities.

The Commissioner advises that the actions related to the development of this recommendation are separate from any actions concerning X-ray intensifying screens that may be taken under the authority of the Medical Device Amendments of 1976 (Pub. L. 94-295) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). Classification of X-ray intensifying screens according to section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) or any subsequent regulations or other actions will be separate actions which will proceed independently of the development of any radiation protection recommendations.

Through its Bureau of Radiological Health, FDA has had an active interest in the development and increased use of X-ray intensifying screens made from the newer phosphors because of the potential of such screens for significantly reducing exposure from medical radiographic examinations. Studies performed in BRH laboratories and elsewhere have demonstrated that exposure reductions of 50 to 90 percent compared to conventional systems are now possible using intensifying screens made from the new generation of phosphors. Images obtained with systems that provide a 50 percent exposure reduction are comparable to those obtained with conventional systems, whereas those systems providing the greatest exposure reduction may be useful only in certain circumstances or for special procedures. In general, an exposure reduction of about one-half of the conventional exposure results from the greater X-ray absorbing efficiency of the new phosphors. Additional exposure reduction is made possible by the increased brightness of the phosphors and their use with film emulsions whose spectral sensitivity has been optimized for the phosphor emissions. Although this additional exposure reduction may degrade image quality, the Commissioner believes there may be applications where this degradation does not result in a significant loss of diagnostic information.

- 24067 -

The Commissioner is considering those actions which the agency should take to encourage the potential reduction in exposure to ionizing radiation that could result from widespread use of the new intensifying screens where they prove to be clinically acceptable. Among the actions being considered is the establishment of an FDA radiation protection recommendation encouraging the use of the new screens. The Commissioner is therefore seeking comment on the utility, need for, and content of such a recommendation as well as information that could be used to develop the recommendation or that could be included in educational programs to promote the use of such screens.

The Commissioner advises that BRH has evaluated prototype intensifying screens which offer more than a 50 percent reduction in patient exposure, compared to conventional calcium tungstate screens, while offering superior or comparable image quality. This evaluation is based on examination of the physical parameters of the images. Most of the commercially available newer film-screen systems appear to be designed to require even less exposure than the prototype screens described above, but unfortunately, result in a compromise of the image quality, such as lower contrast or increased quantum mottle (blotching of the image due to statistical fluctuations in spatial distribution of the image-forming X-rays). The current purchaser may be left in the position of having to compromise some image quality to obtain the exposure reduction afforded by the new systems. The Commissioner encourages manufacturers to offer improved intensifying screen and X-ray film combinations that do not compromise image quality and believes that this should be possible with current technology. The Commissioner sees the interaction of: (1) the electrochemical industry in developing new phosphors, (2) the screen manufacturers in applying these phosphors, and (3) the film manufacturers in developing new emulsions as an example of technology transfer and engineering that is well directed to the national interest in a vital area of public health. Although long term gains may be achieved by developing more efficient phosphors and higher packing densities, the Commissioner hopes that the present gains can be incorporated into general medical practice in the short term.

The Commissioner acknowledges that the adoption of the newer film-screen systems by facilities with established radiology programs may require the solution of certain clinical and technical problems associated with the different characteristics of the newer systems and the use of multiple imaging systems in a single facility. He invites comments defining the type and extent of these problems, as well as information on steps which have been or could be used to overcome these problems.

Clinical users of these systems are invited to submit information on their clinical experience and suggestions concerning the use of currently available systems, together with recommendations for future developments. Manufacturers and others are also invited to submit their current or anticipated solutions to these problems. Such information will be used in determining the need for and content of any recommendations and to support educational efforts designed to encourage the use of the new systems.

To assist in this study and in developing useful recommendations, the Commissioner requests detailed scientific and technical data, as well as comments or suggestions, supported by detailed rationale and justification on the following questions:

1. For what examinations have the newer screen-film combinations been used without loss of diagnostic information, and what are the magnitudes of the exposure reductions realized from their use?

2. For what examinations may image quality be traded for exposure reduction without compromising the diagnostic objectives of the examination, and with which imaging systems has this been satisfactorily accomplished?

3. Do technologists adapt readily to the particular energy (kVp) dependence of these systems? What adjustments of technique are necessary because of the new systems?

4. What procedures should be used by a facility when adopting imaging systems using the newer screens? Should single X-ray systems or entire departments be converted at once to use the new intensifying screens?

5. Can darkroom facilities and procedures be adjusted to effectively operate when different film and screen combinations are used in the same facility?

6. What is the effect of the use of the newer screens on overall system performance and reliability? Does the potential for reduced exposures result in extended X-ray tube lifetime? Can the reduced exposure times possible with the new screens be used to reduce problems due to patient motion?

7. What additional actions should FDA take, in addition to the possible development of an FDA formal recommendation, to foster the use of the newer imaging systems and thereby reduce exposure to radiation?

Individuals or organizations wishing to receive copies of draft recommendations or related documents distributed or made available for review during consideration of this action by the agency may have their names placed on the mailing list by writing to: Division of Compliance (HFX-460), Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Interested persons are invited to participate in developing the proposed recommendation by submitting written comments or data on the subject. Communications on the proposed recommendation should be sent to the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Comments received on or before November 29, 1978, will be considered by the Commissioner in formulating any recommendations on this subject. Recommendations that are developed will be published in the FEDERAL REGISTER as proposals and public comment will be invited.

This notice of intent is issued under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 356, 82 Stat. 1174-1176 (42 U.S.C. 263d)) and under authority delegated to the Commissioner (21 CFR 5.1).

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[FR Doc 78-15063 Filed 6-1-78; 8:45 am]

G. Records and Reports

†50.—Radiofrequency Sealers and Electromagnetic Induction Heating Equipment

†50.1 Proposal—August 24, 1979

– 44 FR 49699 –

[21 CFR Part 1002]

[Docket No. 79N-0260]

Records and Reports: Applicability of Requirements to Manufacturers of Radiofrequency (RF) Sealers and Electromagnetic (EM) Induction Heating Equipment

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to add radiofrequency (RF) sealers and electromagnetic (EM) induction heating equipment to the listing of electronic products for which manufacturers are required to submit initial reports, annual reports, and model change reports. The proposal would also require manufacturers to maintain certain records on these sealer and induction heater products. The agency is taking this action because available data support the contention that currently marketed RF sealers and EM induction heating equipment may present a health hazard to persons exposed to the products.

DATES: Written comments by October 23, 1979.

ADDRESS: Written comments and any supporting documentation to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Richard S. Sternchak, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: FDA has obtained information indicating a need to evaluate a potential radiation hazard to humans. It involves use of RF sealers and EM induction heating equipment designed to emit electromagnetic radiation in the frequency range from 10 megahertz (MHz) to 300 MHz for heating materials. Of particular concern are the industrial, scientific, and medical (ISM) frequency bands centered at 13.56 MHz, 27.12 MHz, and 40.68 MHz. Health and safety personnel from various State and Federal agencies have conducted independent measurement surveys and have corroborated that RF sealers and EM induction heaters emit significant levels of unnecessary radiation in an uncontrolled manner. Institutional groups in several countries have conducted research and testing. Although some experiments have produced inconclusive or negative results, others have indicated biological effects in laboratory animals exposed to these frequencies and levels of electromagnetic radiation. Concern exists because of the ability of the radiation to cause deep body heating and localized rises in tissue temperature that may result in cell death. Copies of the pertinent background data and information supporting the proposal are on file with the Hearing Clerk, Food and Drug Administration (address above).

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The agency is concerned that this electromagnetic radiation may cause similar biological effects in humans, and, therefore, presents a health hazard. Information is now needed on the design and emission characteristics of these sealers and heaters to help the Bureau evaluate the need for promulgating a radiation safety performance standard for the products.

The proposed amendment would add to the specific product listing under § 1002.61(c) (21 CFR 1002.61(c)) all RF sealers and EM induction heating equipment operating in the 10 MHz to 300 MHz frequency range. It is intended to apply to products whose primary function is to heat materials controllably by emitting electromagnetic radiation within the specified frequency range. This rule would include all products used in industry where RF fields are the mechanism of energy transfer in such processes as sealing, dielectric welding, fastening, fusing, molding, embossing, drying or gluing materials including, but not limited to, plastics, wood, paper, rubber, textiles, and fibers. Listing these products under § 1002.61(c) would in turn require the submission of initial reports under § 1002.10 (21 CFR 1002.10), annual reports under § 1002.11 (21 CFR 1002.11), and model change reports under § 1002.12 (21 CFR 1002.12). In addition, manufacturers will be required to maintain certain records under § 1002.30 (21 CFR 1002.30) and comply with the preservation and inspection of records provisions of § 1002.31 (21 CFR 1002.31). Manufacturers of RF sealers and EM induction heaters currently are required by § 1002.20 (21 CFR 1002.20) to report any known injuries resulting from the products' use to the Bureau of Radiological Health, Food and Drug Administration. This proposal would not affect that requirement. Initial reports on the products would be required to be submitted within 90 days of the effective date of this proposed amendment, or prior to introduction of a sealer or heater product into commerce, whichever is later (21 CFR 1002.10). This proposed rule is to become effective 30 days after the date of publication of the final rule in the FEDERAL REGISTER.

The Radiation Control for Health and Safety Act of 1968 gives the agency ample powers to require the records and reports which are the subject of this proposal. Section 360A(b) of the act (42 U.S.C. 263i(b)) requires manufacturers of electronic products (including RF sealers and EM induction heating equipment) to establish and maintain records, make reports, and provide information that the agency reasonably requires to enable it to determine whether the manufacturers are complying with the act. Subsection (c) of that section requires manufacturers to make available to the agency performance data and other safety data as may be required for the agency to carry out the purposes of the act.

The Food and Drug Administration has determined that this document does not contain an agency action covered by § 25.1(b) (21 CFR 25.1(b)), and consideration by the agency of the need for preparing an environmental impact statement is not required.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 360A, 82 Stat. 1182-1184 (42 U.S.C. 263i)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 1002 be amended in § 1002.61 by adding new paragraph (c)(5), to read as follows:

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§ 1002.61

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[FR Doc. 79-26033 Filed 8-23-79; 8:45 am]

II. Performance Standards for Electronic Products: General

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D. Variances

1.—Performance Standards

†1.3 Proposal—February 6, 1979

– 44 FR 7149 –

[21 CFR Part 1010]

[Docket No. 78N-0375]

PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

Variances from Performance Standards

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: This proposal would amend the administrative procedures for ruling on applications for variances from performance standards for electronic products. The procedures would no longer include publication of variance approvals in the FEDERAL REGISTER because experience has shown that such notices are not necessary for adequate protection of the public health.

DATE: Comments by April 9, 1979. The final rule based upon this proposal will be effective upon its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Melvyn R. Altman, Bureau of Radiological Health (HFX-460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: In a final rule published in the FEDERAL REGISTER of April 18, 1974 (39 FR

13879), the Food and Drug Administration (FDA) established procedures for ruling on applications for variances from provisions of the performance standards for electronic products issued under 21 CFR Subchapter J. These procedures provide for publication in the FEDERAL REGISTER of variances approved by the Director, Bureau of Radiological Health.

An approved variance becomes effective no sooner than 30 days after the FEDERAL REGISTER notice of the approval, unless objections and supporting documentation are received within 30 days. If objections are received, the effective date of the variance is stayed until the Director rules on the objections.

In establishing these procedures, FDA intended to make information and actions on variances readily available to the public and assure interested and affected parties an opportunity to comment on approved variances. However, after more than 4 years' experience with the variance procedures, it is clear that the FEDERAL REGISTER notice has not served its intended purpose. Rather, the procedure needlessly expends agency resources and delays the effective date of approved variances, which often imposes an unjustified economic burden on manufacturers. The agency has published 16 variances and has received only 2 letters of objection, both of which resulted from misunderstandings. Thus, no variance approval has been altered by its publication in the FEDERAL REGISTER.

It is the opinion of the agency that suitable notification of approved variances can be given without publishing them in the FEDERAL REGISTER and that this publication is not required by the Administrative Procedure Act because a variance approval is not a substantive rule of general applicability (5 U.S.C. 552, 553). The Bureau of Radiological Health publishes a bulletin, widely distributed and available to any person on request, that includes a discussion of approved variances. In addition, State radiation control authorities are consulted concerning applications for variances as well as actions taken when those agencies either have special information on the application or would be substantially affected by it. The agency believes that interested parties will be adequately informed about approved variances by these means.

No environmental impact statement or environmental impact analysis report is required under § 25.1(b) (21 CFR 25.1(b)) because this procedural amendment would not significantly affect the quality of the environment.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)), and under authority delegated to him (21 CFR 5.1), FDA proposes to amend Part 1010 by revising § 1010.4(c) as follows:

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§ 1010.4

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[FR Doc. 79-3799 Filed 2-5-79; 8:45 am]

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†1.4 Final Regulation—August 17, 1979

- 44 FR 48190 -

[Docket 78N-0375]

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

Variances From Performance Standards

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The Food and Drug Administration (FDA) amends the administrative procedures for ruling on applications for variances from performance standards for electronic products. As a result of this amendment, the procedures no longer include formal publication of variance approvals in the FEDERAL REGISTER because experience has shown that such notices are not necessary for adequate protection of the public health. The agency will, however, publish notices of availability of approved variances in the FEDERAL REGISTER.

EFFECTIVE DATE: September 17, 1979.

FOR FURTHER INFORMATION CONTACT:

Melvyn R. Altman, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 6, 1979 (44 FR 7149), FDA proposed to amend the administrative procedures in § 1010.4 (21 CFR 1010.4) for ruling on variance applications. The agency proposed to delete the requirement that variance approvals be published in the Federal Register with a 30-day objection period before the variance could become effective.

The agency received five comments on the proposal—four from manufacturers of electronic products and one from a manufacturer's consultant. The following is a summary of the comments received and FDA's responses to them:

1. Two comments stated that the current regulation caused unnecessary delays and costs. Both comments fully endorsed the proposed amendment to the regulation. Two other comments supported the proposal but urged that concerned parties be informed of approved variances. One of the comments suggested announcement in the newsletter published by the Bureau of Radiological Health (as was discussed in the proposal). Another comment asked that the Bureau adopt a policy of informing interested manufacturers of approved variances.

The agency accepts the suggestion that manufacturers and other interested parties be informed but has decided to inform them routinely by issuing notices of availability of approved variances in the Federal Register. The notice will include only basic information on the variance and will indicate availability of the complete variance from the office of the Hearing Clerk. The notice of availability differs from the present notice of variance approval in that the latter notice contains all the details of the variance and provides a 30-day objection period. The new procedure provides for a brief notice of availability and the effective date of the variance would not depend on it. The new procedure would therefore inform concerned parties of approved variances while expediting the variance approval process and eliminating what experience has shown to be the needless expenditure of agency resources on the publication of the details of all variances. Accordingly, the final regulation has been changed to provide for the routine issuance of a notice of availability.

2. One comment opposed the proposal on the ground that informing interested parties of approved variances by means other than the Federal Register would not be as prompt and reliable as the current procedures.

The agency believes that this comment has merit and, as discussed in paragraph 1, the final regulation has been modified to provide for publication of a notice of availability of approved variances. The effective date of a variance will not depend on this Federal Register notice, and variances will not be delayed unnecessarily.

Minor editorial changes are being made in § 1010.4(c)(3) and (4) for purposes of clarification.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 1010 is amended by revising § 1010.4(c) to read as follows:

- 48191 -

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§ 1010.4

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[FR Doc. 79-25448 Filed 8-16-79; 8:45 am]

III. Ionizing Radiation Emitting Products

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E. Diagnostic X-Ray Systems

2.—Amendment of Performance Standards

†2.3 Proposal—July 14, 1978

– 43 FR 30303 –

[21 CFR Part 1020]

[Docket No. 75N-0071]

DIAGNOSTIC X-RAY SYSTEMS AND THEIR MAJOR COMPONENTS

Amendments to Performance Standard

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: This is a proposal to amend the performance standard for diagnostic X-ray systems and their major components to: revise the statement of applicability with respect to cassette holders and add a definition for "cassette holder"; revise the definition for "leakage technique factors" and the conditions for measuring the leakage radiation from the diagnostic source assembly; clarify the requirements for spot-film X-ray field limitation; and require that certain types of fluoroscopic X-ray systems be provided with the means for stepless adjustment of the X-ray field size.

DATE: Comments by September 12, 1978.

ADDRESS: Written comments to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

John C. Taschner, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1960.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of June 11, 1975 (40 FR 24909), the Commissioner of Food and Drugs issued several proposed amendments to the diagnostic X-ray systems performance standard. As a result of comments received, proposed amendments concerning spot-film X-ray field limitation and stepless adjustment of the X-ray field size on image-intensified fluoroscopic systems were withdrawn from the final rule published in the FEDERAL REGISTER of February 25, 1977 (42 FR 10983), so that further evaluation of these proposals would not delay promulgation of the remaining amendments. In addition, one comment recommended that definitions be included in § 1020.30(b) (21 CFR 1020.30(b)) for "cassette holder" and "cassette tray" because these terms have been used frequently in implementing the standard without the terms being defined. Also, two comments expressed concern over the definition of "leakage technique factors" as it relates to beam-limiting devices used in mammography.

Based on these comments and further evaluations by the Bureau of Radiological Health (BRH), the Commissioner now proposes the following specific amendments:

1. The unqualified phrase "cassette holders" would be deleted from § 1020.30 (a)(1)(i) (21 CFR 1020.30(a)(1)(i)). In its stead, the Com-

missioner proposes to substitute the phrase "vertical cassette holders mounted in a fixed location and cassette holders with front panels." This proposed revision is consistent with FDA policy that only these cassette holders require certification and that cassette trays mounted under stationary radiographic-fluoroscopic tables do not require certification. For clarification, "cassette holder" would be defined in new § 1020.30(b)(57). A separate definition for "cassette tray" is unnecessary because the Commissioner considers cassette trays to be one type of cassette holder.

2. The Commissioner proposes to revise the definition of "leakage technique factors" in § 1020.30(b)(21) to specify factors associated with the diagnostic source assembly rather than the X-ray tube housing assembly. He also proposes to amend § 1020.30(k) to require positive means to limit the technique factors such that the leakage technique factors are not exceeded if the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly.

The current leakage radiation requirement in § 1020.30(k) applies to the diagnostic source assembly, defined in § 1020.30(b)(11) as the tube housing assembly with a beam-limiting device attached. But a rigorous interpretation of the standard has led to the interpretation that the leakage radiation limit should be met with the X-ray tube operated at its leakage technique factors, defined in terms of the tube housing assembly and specifically in terms of the maximum rated peak tube potential. Thus, a beam-limiting device not rated for the maximum peak tube potential for the tube housing assembly could not be used with that tube-housing assembly even though it may never be operated above the rating of the beam-limiting device. The BRH published policy, however, has been to test for leakage radiation at the maximum potential of the compatible X-ray control and generator. Thus, a beam-limiting device used for mammography and rated for low kilovoltage, for example, may be listed by the manufacturer as being compatible with an X-ray tube rated at 150 kilovolts peak (kVp), provided it is installed with a control interlocked so as to prevent X-ray production above the peak tube potential for which the beam-limiting device was rated. The proposed revision of § 1020.30(b)(21) would make the standard consistent with this BRH policy.

The proposal to amend § 1020.30(k) to require that positive means be provided to limit the technique factors when the maximum-rated peak tube potential for the diagnostic source assembly is less than the rated peak tube potential of the tube-housing assembly is necessary to insure that excessive leakage radiation does not result from exceeding the leakage technique factors for the diagnostic source assembly.

The proposed revisions of § 1020.30(b)(21) and § 1020.30(k) would necessitate the following additional changes in the provisions of the standard:

Section 1020.30(h)(2) would be revised to require each tube-housing manufacturer to state the leakage technique factors for each combination of tube housing assembly and beam-limiting device which the manufacturer states as being compatible. Likewise, § 1020.30(h)(4) would be revised to require each beam-limiting device manufacturer to state each combination of beam-limiting device and tube housing assembly which the manufacturer specifies as being compatible. In addition, the current provision in § 1020.30(h)(4)(i) would be deleted, as this requirement is already contained in § 1020.30(g).

3. Section 1020.31(g)(1) (21 CFR 1020.31(g)(1)), concerning X-ray field limitation on systems equipped with spot-film devices, would be revised to remove an ambiguity.

Section 1020.31(g)(1) currently requires that means be provided between the X-ray source and the patient for adjustment of the X-ray field size to the size of that portion of the film which has been selected on the spot-film selector, and that the adjustment shall be automatic except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. But the provision does not specify the general characteristics of the means to be provided for adjustment of the X-ray field size when it is smaller than that of the selected portion of the film. The Commissioner proposes to remove this ambiguity by adding a statement to § 1020.31(g)(1), that when the X-ray field size is less than the size of the selected portion of the film, adjustment of the field size shall be accomplished only at the operator's option. The Commissioner intends that adjustment of the X-ray field for spot films always be automatic if the fluoroscopic shutter settings are such that the X-ray field would be larger than the selected spot film format. If the fluoroscopic shutter settings produce an X-ray field smaller than the selected spot film format, then further adjustment of the shutters should only be accomplished at the option of the operator. A system would be permitted that provides a choice of two modes of operation, such that in one mode the beam-limiting device would adjust automatically to the selected spot-film size; while in the other mode, the beam-limiting device would not automatically adjust to the selected spot-film size when the size of the X-ray field at the film is smaller than the selected spot-film size.

4. Section 1020.32(b)(2)(iv) (21 CFR 1020.32(b)(2)(iv)) concerning image-intensified fluoroscopic systems would be revised to require that the systems with variable source-image receptor distance (SID) and/or with an image intensifier having a maximum visible area greater than 300 square centimeters (cm^2) be provided with means for stepless adjustment of the X-ray field size. Equipment with a fixed SID and a maximum visible area of 300 cm^2 may be provided with either stepless adjustment of the X-ray field or other means, such as a sliding aperture plate, to limit further the X-ray field to 125 cm^2 or less at the plane of the image receptor. In addition, the requirement for a minimum field size equal to or less than 5 by 5 cm would be deleted for systems without stepless adjustment.

Many comments objected to the June 11, 1975 proposed amendment to § 1020.32(b), requiring that all fluoroscopic X-ray systems be provided with the means for stepless adjustment of the X-ray field size. Several comments stated that while they had no objection to its application to stationary general-purpose fluoroscopic systems, they were concerned that the addition of stepless beam-limiting devices to mobile and some special purpose image-intensified fluoroscopes, which operate at a fixed SID, would interfere with their intended use. The comments stated that such systems are frequently used in operating rooms during orthopedic, neurologic, and cardiac surgery procedures, and they must be light and compact for rapid positioning over a wide range of angles. They expressed their concern that the addition of stepless beam-limiting devices would add weight and complexity to such systems, interfere with positioning, and make them more difficult to use. Some comments expressed doubt that significant radiation protection would be gained because mobile fluoroscopic systems are usually fitted with 6- or 7-inch image intensifiers, and further reduction of the field size is not desired during most diagnostic procedures.

A review of manufacturers' initial reports confirmed the comments that mobile and stationary "C-arm" type of fluoroscopes, which operate at a fixed SID, are fitted with 6- or 7-inch image intensifiers, the largest having an input phosphor area of approximately 230 cm^2. By contrast, stationary general purpose fluoroscopic systems are equipped with 9-inch or larger image intensifiers, and the SID is variable. The smallest image intensifier in the 9-inch class is a 22 cm tube with an input phosphor area of 380 cm^2. Thus, a maximum visible area of 300 cm^2 provides a logical breakpoint for the stepless field limitation requirement. This is consistent with the comments received and with the International Electrotechnical Commission's Standard Publication 407, which requires continuously adjustable collimation where the image receptor area of the image intensifier exceeds 300 cm^2.

Section 1020.32(b)(2)(iv) currently requires, in part, that the minimum field size at the greatest SID shall be equal to or less than 5-by-5 cm. The proposed amendment would eliminate this requirement for image-intensified fluoroscopic systems equipped with stepped field limitation, but would require that these systems be provided with the means to limit further the X-ray field to an area of 125 cm² or less. The 5-by-5-cm minimum field-size requirement is being deleted for stepped beam-limiting devices because the requirement was originally intended to apply only for stepless beam limitation and has no clinical utility for fluoroscopic systems fitted with stepped beam-limiting devices. Because of the limited space available for stepped apertures in this type of beam-limiting device, such a requirement could preclude the use of another, more useful aperture.

The proposal that means be provided to permit further limitation of the fluoroscopic X-ray field to 125 cm² or less is necessary for systems fitted with stepped beam-limiting devices to allow the operator to reduce the beam size and thereby reduce patient exposure in situations where the use of full field is not clinically necessary. The basis for the 125 cm² value is that it is the minimum field size considered by the BRH to be clinically usable.

PROPOSED EFFECTIVE DATE

It is proposed that these amendments become effective on the date of publication of the final regulation in the FEDERAL REGISTER. This early effective date is considered feasible because the new provisions contained in the regulation are for the purpose of clarification and are consistent with interpretations that have been issued previously by the agency. Because the proposed amendment in § 1020.32 (b)(2)(iv) (21 CFR 1020.32(b)(2)(iv)) would not require the modification of designs or quality control or the submission of additional reports, it is proposed that this amendment also become effective on the date of publication of a final regulation in the FEDERAL REGISTER.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes that Part 1020 be amended as follows:

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Part 1020

§ 1020.30
§ 1020.31

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[FR Doc 78-19137 Filed 7-13-78; 8:45 am]

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†2.4 Final Regulation—May 22, 1979

- 44 FR 29653 -

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

[Docket No. 75N-0071]

Diagnostic X-Ray Systems and Their Major Components; Amendments to Performance Standard

AGENCY: Food and Drug Administration.

ACTION: Finale Rule.

SUMMARY: The Food and Drug Administration (FDA) amends the performance standard for diagnostic x-ray systems and their major components (1) to revise the statement of applicability with respect to cassette holders and add a definition for "cassette holder"; (2) to revise the definition for "leakage technique factors" and the conditions for measuring the leakage radiation from the diagnostic source assembly; (3) to clarify the requirements for spot-film x-ray field limitation; and (4) to require that certain types of fluoroscopic x-ray sys-

tems be provided with the means for stepless adjustment of the x-ray field size.

EFFECTIVE DATE: June 21, 1979.

FOR FURTHER INFORMATION CONTACT:

Raymond P. Coakley, Jr., Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of June 11, 1975 (40 FR 24909), FDA issued several proposed amendments to the diagnostic x-ray systems performance standard. As a result of comments received, proposed amendments concerning spot-film x-ray field limitation and stepless adjustment of the x-ray field size on image-intensified fluoroscopic systems were withdrawn from the final rule published in the FEDERAL REGISTER of February 25, 1977 (42 FR 10983) so that further evaluation of these proposals would not delay promulgation of the remaining amendments. In addition, one comment recommended that definitions be included in § 1020.30(b) (21 CFR 1020.30(b)) for "cassette holder" and "cassette tray" because these terms have been used frequently in implementing the standard without the terms being defined. Also, two comments expressed concern over the definition of the term "leakage technique factors" as it relates to beam-limiting devices used in mammography.

Based on these comments and further evaluations by the Bureau of Radiological Health (BRH), FDA proposed in the FEDERAL REGISTER of July 14, 1978 (43 FR 30303), further amendments to the diagnostic x-ray standard to deal with the provisions withdrawn from the February 25, 1977 final rule. Interested persons were given until September 12, 1978, to submit comments on the proposal.

One comment from an individual suggested that one requirement in addition to those proposed was needed. The comment urged that § 1020.31(g)(1) (21 CFR 1020.31(g)(1)) require that the x-ray field size be increased to the larger format only when the radiographic exposure switch for the spot-film has been energized. This operation is in contrast to an increase to larger format occurring whenever the fluoroscopic switch is released. In other words, an expansion of the radiation field should be permitted only when the larger field is needed, rather than whenever the smaller fluoroscopic field is not needed. The comment argued that, in addition to reducing the radiation given the patient during the contraction of the field, this feature would presumably decrease wear on the automatic collimator. The comment stated that some units automatically adjust the collimation to the larger spot-film size every time the fluoroscopic switch is released and readjust to the smaller fluoroscopic size only when the fluoroscopic switch is energized.

The agency advises that the automatic operation suggested by the comment is required by the existing standard. Section 1020.31(g)(1) of the standard requires that the x-ray field size match the portion of the film selected by the spot-film device when the film is to be exposed. If the field before selection is larger than necessary, the field must be automatically reduced to a matching size. If, however, the field before selection is smaller than necessary, it can be increased to matching size only by operator intervention. The standard permits a system that allows the beam-limiting device to adjust automatically to the spot-film size selected by the operator's intervention. An alternative system could require additional operator intervention to adjust the field size to a larger spot-film size. In such a system, only the fluoroscopic image would be produced on film, unless the operator manually increased the image area.

Although the comment does not require a change in the standard, it does identify a potential area of noncompliance with the current standard. The agency intends to investigate at the manufacturer's level to determine whether the products described should be declared noncompliant.

FDA, thus, is publishing the amendments unchanged as final regulations.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 1020 is amended as follows:

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Part 1020

§ 1020.30
§ 1020.31
§ 1020.32

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[FR Doc. 79-15720 Filed 5-21-79; 8:45 am]

8.—Radiation Safety Performance Standards

†8.3 Partial Withdrawal of Advance Notice of Proposed Rulemaking—September 26, 1978

- 43 FR 43473 -

[21 CFR Part 1020]

[Docket No. 75N-0046]

DIAGNOSTIC X-RAY EQUIPMENT

Partial Withdrawal of Advance Notice of Proposed Rulemaking

AGENCY: Food and Drug Administration.

ACTION: Partial Withdrawal of Advance Notice of Proposed Rulemaking.

SUMMARY: The agency is withdrawing parts of an advance notice of proposed rulemaking concerning the diagnostic X-ray performance standard. Information received in response to the document and data developed since its publication have led the agency to reconsider the need to amend the performance standard for diagnostic X-ray systems and their major components as considered in the document.

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EFFECTIVE DATE: September 26, 1978.

FOR FURTHER INFORMATION CONTACT:

Joseph Wang, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: In an advance notice of proposed rulemaking published in the FEDERAL REGISTER of June 19, 1975 (40 FR 25830), the Commissioner of Food and Drugs announced that he was considering amending the performance standard for diagnostic X-ray systems and their major components under §§ 1020.30, 1020.31, and 1020.32 (21 CFR 1020.30, 1020.31, and 1020.32) to add certain requirements for dental X-ray equipment and other requirements for all X-ray equipment. The advance notice of proposed rulemaking was issued in accordance with Food and Drug Administration (FDA) policy of early public disclosure of rulemaking activities, and it was intended to solicit comments from interested persons concerning the amendments under consideration. Data and information collected by the Bureau of Radiological Health, coupled with 14 comments from X-ray equipment users and 12 from X-ray equipment manufacturers, have caused the Commissioner to reconsider the proposals discussed in the advance notice of proposed rulemaking. Comments from these interested persons will be addressed later by FEDERAL REGISTER notices relating to the continuing issues in the advance proposal. This current document withdraws some of the proposals considered in the advance notice document and informs the public of the current status for those still under consideration.

1. *Dental X-ray equipment*—a. In the June 19, 1975 document, the Commissioner advised that he was considering establishing a limit on the leakage radiation from the diagnostic source assembly at the minimum source-to-skin distance (SSD) for which a dental X-ray machine is used. Because most dental X-ray equipment is used at short SSD's and is frequently installed in confined quarters, the Commissioner believed a leakage limit at the minimum SSD would reduce patient exposure from such radiation. But leakage radiation levels now being found are

only a small fraction of that permitted by the current standard. In addition, calculations of X-ray radiation dose to the patient indicate that even if leakage radiation occurred at the permissible limit, unwanted X-ray exposure in the vicinity of the patient is quite low, if high-speed film is used, and would be a small percentage of the useful beam. Further, setting a minimum SSD leakage radiation limit would require measurement of the leakage radiation for dental X-ray equipment at SSD's shorter than the 1 meter specified by the current regulation, § 1020.30(k) (21 CFR 1020.30(k)). This change would require additional test equipment not now available to the manufacturers of diagnostic X-ray systems. The Commissioner is concerned that additional test equipment would lead to increased cost of medical care without demonstrated dose savings and therefore cannot be justified. For these reasons, the Commissioner has determined that no further action will be taken at this time concerning this issue, and he withdraws the proposal.

b. In the June 19, 1975 document, the Commissioner announced consideration of means to reduce patient dose and to improve the quality of dental radiographs by changing requirements for dental X-ray beam quality. Requirements under consideration included specifying minimum peak X-ray tube potential and/or adding specifications on the X-ray spectrum for dental X-ray systems. The agency will continue efforts in this area and will announce its activities in future FEDERAL REGISTER publications under the docket number found in the heading of this document.

c. In the June 19, 1975, document, the Commissioner advised that the Bureau of Radiological Health was evaluating the use of open-ended, shielded, position-indicating devices (PID's) and assessing the effect of such devices on possible X-ray exposure reduction during typical dental X-ray procedures. This evaluation was completed, and a report was submitted to the Commissioner on August 12, 1975 (a copy of this report is on file with the Hearing Clerk (HFA-305), Food and Drug Administration). The report concludes that the long, open-ended, shielded PID could reduce the dose when used with a long-cone, paralleling technique and that its use with such technique is to be encouraged. But when used with the bisecting angle technique, the dose to the patient could be larger than with a pointer cone (closed-ended PID). No additional data are available to the agency to contradict the August 12, 1975, evaluation, and the Commissioner concludes that Federal requirements concerning open-ended PID's are unwarranted at this time. Interested persons who initiated this issue by inquiries to the Bureau of Radiological Health were advised of the Commissioner's conclusions in a letter that was sent to them on January 26, 1978 (copy on file with the Hearing Clerk). This proposal is withdrawn, and FDA is currently contemplating no further action concerning requirements for open-ended PID's.

d. In the June 19, 1975, document, the Commissioner announced consideration of an amendment to the standard to specify location of dental X-ray equipment exposure controls.

The Commissioner believes that a requirement concerning exposure control location may reduce operator exposure by allowing operation of the X-ray equipment from a specified minimum distance from the X-ray source. However, because exposure control location for the most part is determined by independent dealers and varies with the design of each dental suite, the Commissioner believes that this type of requirement can be more appropriately regulated by State radiation control agencies that are responsible for regulation of facility design. Thus, this proposed revision is withdrawn.

2. *All X-ray equipment*—a. In the June 19, 1975, document, the Commissioner announced consideration of the need to amend the general provisions of §§ 1020.30, 1020.31, and 1020.32 to require manufacturers of film-screen combinations to supply information to allow users to match screen emission characteristics with film sensitivity characteristics. As a related matter the Commissioner also considered es-

tablishing performance requirements for film cassettes to assure proper film-screen contact.

Under the Medical Device Amendments of 1976 (Pub. L. 94-295) amending the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), all medical devices intended for human use must be classified into one of three regulatory classes (categories) based on the extent of control necessary to assure the safety and effectiveness of each device. The Radiological Device Classification Panel has recommended to the Commissioner that X-ray film be classified as a Class I device. Devices under this category are subject only to general controls and not standards or premarket approval. The Commissioner is withdrawing the proposal and is deferring action concerning film-screen combinations and film cassettes until after a final decision is made on the classification of X-ray film under the Food, Drug, and Cosmetic Act. Further action under authority of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263f)) may be considered in a future FEDERAL REGISTER publication under a separate docket number.

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b. Finally, the Commissioner announced in the advance notice that he was considering amending the regulations to require that manufacturers of X-ray tubes specify focal spot size of the tubes and describe the manner in which focal spot size was determined.

The Commissioner recognizes the technical pitfalls associated with the quantification of focal spot size. Besides its size, the actual focal spot of a diagnostic X-ray tube must also be quantified in terms of the intensity distribution. For most X-ray tubes presently in use, the focal spot intensity distribution is nonuniform, usually having a twin peaked distribution. Its size and intensity distribution can further be affected by changes in voltage and current applied to the X-ray tube. The focal spot often is enlarged as current is increased and voltage is reduced. The Commissioner has determined that because the techniques for the quantification of focal spot size are still in the evolving stage, the issuance of a regulatory standard which specifies a particular method for focal spot determination may not be appropriate at this time. The Radiological Device Classification Panel examined this problem in relation to its review of X-ray tubes and suggested that labeling requirements concerning focal spot size would be useful to the X-ray tube user. The Commissioner agrees that information concerning X-ray tube focal spot size would be of value to the user of the tube, and believes this can be appropriately accomplished through alternative means such as a voluntary standard. Thus, the Commissioner is now withdrawing the proposal for a regulatory standard but advises that this issue may be considered under a separate docket number in a future FEDERAL REGISTER publication.

This notice is issued under the authority of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263f)) and under authority delegated to the Commissioner (21 CFR 5.1).

The documents concerning these issues and all related correspondence, except information covered by the confidentiality provisions of section 360A(e) of the Public Health Service Act (42 U.S.C. 263i(e)), have been placed on public display in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen Monday through Friday from 9 a.m. to 4 p.m., except on Federal legal holidays.

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Part 1020

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[FR Doc. 78-26945 Filed 9-25-78; 8:45 am]

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†8.4 Proposal—January 30, 1979

- 44 FR 5908 -

[21 CFR Part 1020]

[Docket No. 75N-0046]

DIAGNOSTIC X-RAY SYSTEMS AND THEIR MAJOR COMPONENTS

Proposed Amendment to Performance Standard

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the performance standard for diagnostic x-ray systems to modify the beam quality (half-value layer) provision of the standard for dental x-ray systems designed for use with intraoral image receptors. The purpose of this amendment is to reduce unnecessary x-radiation exposure to the patient that can result from low voltage, low filtration dental x-ray systems.

DATES: Comments by April 30, 1979, the Food and Drug Administration proposes that the final amendment become effective 1 year after date of publication of the final rule in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

John C. Taschner, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: Many investigators have measured the x-ray exposure to patients or phantoms exposed to dental radiographs to determine those refinements of technique that would result in minimum patient exposure while yielding maximum diagnostic information. The influence of beam quality (waveform, peak accelerating potential, and filtration) on patient exposures and image characteristics has been the focus of numerous investigations, summarized in a literature review by Saulnier and Barr (Ref. 1). A study by Lee (Ref. 2) showed marked increases in the entrance skin, mandibular bone marrow, thyroid, eye, and integral doses as the peak tube potential was decreased from 72 to 44 kilovolts peak (kVp). The entrance skin dose, for example, is approximately 7 times higher for the low-kilovoltage technique, although the amount of exposure at the film for both cases is about the same. There was little apparent difference in the doses as the tube potential was raised from 72 kVp to 91 kVp. The results of this study are in good agreement with those reported by Alcox and Jameson (Ref. 3) in a study conducted under clinical conditions. These studies show that among today's acceptable dental radiographic practices, those employing the lowest peak tube potentials and the least filtration will deliver the greatest radiation doses per film to the dental patient. These high-dose techniques are permitted by current voluntary standards (Refs. 4 and 5) and § 1020.30(m)(1) (21 CFR 1020.30(m)(1)) of the diagnostic x-ray system performance standard.

The higher entrance skin doses result from the fact that more than half of the photons in the spectrum of a low kilovoltage beam are below 27 kiloelectron volts (keV). These photons are readily absorbed by the intervening tissues between the skin and film, contributing heavily to patient dose, but are relatively inefficient in producing a radiographic image. For example, 20 and 40 keV photons have approximately the same mass absorption coefficient in silver, yet the absorption coefficient of the 20 keV photon is 8 times higher in soft tissue and 12 times higher in bone than that of the 40 keV photon, even though the amount of exposure required at the x-ray film to produce a satisfactory dental radiograph is about the same (Ref. 2).

The FDA proposes to amend § 1020.30(m)(1) to require that the half-value layer (HVL) of the useful beam of all dental x-ray systems operating at 70 kVp and below be equivalent to at least 1.5 millimeters (mm) of aluminum (Al). Dental x-ray systems operating above 70 kVp would continue to meet the requirements of Table I of § 1020.30(m)(1). The current provisions of the standard require a minimum HVL of 1.2 mm Al at 50 kVp and

1.5 mm Al at 70 kVp. The 50 kVp systems currently produce a normalized entrance skin-to-film exposure ratio of about 18 to 1, a greater ratio than the FDA believes should be tolerated. (Even higher entrance skin-to-film ratios may occur at kilovoltages lower than 50 kVp.) By establishing 1.5 mm Al as the lower HVL limit, the entrance skin-to-film ratio can be reduced to about 13 to 1, closer to the 10 to 1 ratio proposed as the maximum in a draft amendment distributed by the Bureau of Radiological Health (BRH) in October 1975. To achieve an HVL of 1.5 mm Al at 50 kVp, the total filtration in the primary x-ray beam would be about 2.5 mm Al equivalent.

The FDA has taken several actions allowing interested persons to participate in the development of the proposed amendment. The basic concept was presented by BRH on September 19, 1974 at the 12th meeting of the Technical Electronic Product Radiation

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Safety Standards Committee (TEPRSSC). A notice of intent to amend the beam quality provision of the standard with respect to dental x-ray systems, published in the FEDERAL REGISTER of June 19, 1975 (40 FR 25830), invited the public to participate in the development of the proposed amendment by submitting written comments concerning the amendment. A draft of the proposal and supporting rationale was reviewed on September 18, 1975 at the 13th meeting of TEPRSSC. This draft was subsequently distributed on October 1, 1975 to manufacturers, professional associations, State radiation control agencies, and other interested persons on the Bureau's mailing list, inviting comment on the proposal. The draft, the comments received, and the summary of advisory committee meetings are on file with the Hearing Clerk, FDA. In developing this proposal, FDA has considered all comments received on the notice of intent and the October 1, 1975 draft amendment and rationale document. A summary of the comments and the FDA's responses follows:

1. Several comments recommended establishing a minimum peak tube potential (kVp) provision for dental x-ray machines rather than changing the HVL requirements of § 1020.30(m). Suggested minimum values ranged from 50 to 65 kVp.

The purpose of establishing HVL requirements specifically for dental x-ray systems designed for use with intraoral image receptors is to provide x-ray beam qualities that would yield the maximum diagnostic information with the minimum dose to the patient. The FDA believes that to adopt the suggestions would simply cause the elimination of low kilovoltage dental x-ray machines.

2. Several comments disagreed with establishing minimum HVL requirements based on an arbitrary set entrance skin-to-film exposure ratio of 10. They argued that this approach, while eliminating low kilovoltage, low filtration techniques that are responsible for high patient exposure, would permit the use of high kilovoltage, low filtration techniques that would result in patient exposures greater than those presently allowed. These comments, in general, disagreed with the proposal to lower the current minimum HVL requirements at the high kilovoltages but supported increasing the minimum HVL requirements at the lower kilovoltages to upgrade the beam quality of these dental x-ray systems.

The FDA agrees with these comments and has modified the proposed amendment accordingly.

3. Two comments from State radiation control agencies expressed concern that their regulations, which require 2.5 mm Al filtration at 70 kVp and above and 1.5 mm Al filtration below 70 kVp, would be in conflict with the proposed amendment. One comment also stated that dental x-ray equipment meeting the current beam quality standard would become substandard after the effective date of the final amendment and questioned whether the States should allow continued use of such equipment.

The revised x-ray beam quality amendment would apply only to dental x-ray systems manufactured on or after the effective date of the amendment and that operate at about 70 kVp and below. According to section 360F of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263n), State regulations would have to be identical if they apply to newly manufactured x-ray systems and address the same aspect of performance.

Manufacturers' and assemblers' reports filed at BRH from August 1974 through June 1976 indicate that only about 10 percent of the dental x-ray systems currently in use or in the "used" equipment market would not meet the proposed amendment, if the amendment were to be applied by States to equipment purchased before the effective date of the amendment. Because these x-ray systems have been shown to contribute unnecessary x-ray exposure, the FDA encourages State regulatory agencies to consider actions that would require these x-ray systems either to be modified to meet the new proposed provisions or to be phased out of use.

4. One comment asked whether manufacturers would be permitted to comply with the amendment before the effective date.

It is FDA's policy to permit manufacturers to comply with a performance standard for electronic products or an amendment to a standard after its publication as a final rule in the FEDERAL REGISTER but before the effective date if the manufacturers have filed appropriate amendments to their reports under Part 1002 (21 CFR Part 1002). In this case, compliance with the amendment would also be compatible with compliance with existing regulations. Therefore, although the FDA proposes that the amendment will not become effective until 1 year after it is published, manufacturers could adopt performance requirements compatible with the amendment at any time, and the FDA encourages early compliance.

5. One comment stated that establishing different HVL requirements for dental x-ray systems designed for intraoral and extraoral film radiography would prevent a practitioner from using a dental x-ray system for both techniques.

Generally, x-ray systems not capable of operating at 70 kVp and above are unsuitable for extraoral film radiography. For those dental x-ray systems that are designed for the higher kVp range (70 kVp and above), the current minimum beam quality requirements in the standard would be met.

6. One comment stated that the proposed HVL requirements may create difficulties in taking certain intraoral radiographs, namely (a) sialography, (b) detection of low-contrast foreign bodies, (c) fluid study of sinus examination, and (d) soft tissue examinations in general. These examinations all require low tube potentials (40 to 50 kVp) with very little filtration (0.5 to 1 mm Al). If these examinations are made with heavily filtered x-rays at 50 kVp, the exposure times must be increased substantially due to the low tube current of most dental x-ray machines, resulting in unacceptable motion unsharpness in the radiographs.

Little evidence was presented in the written comments received by BRH in regard to the need, based on imaging demands, for the continued allowance for low kilovoltage, low filtration dental x-ray systems. Radiographic practice using these units has repeatedly been shown to result in considerably greater radiation doses to the dental patient. According to assemblers' reports filed at BRH, the low kilovoltage, low filtration dental x-ray systems constituted only about 10 percent of total market from August 1974 through June 1976. The need for such systems is, therefore, not significant, and most dental radiographers do without such equipment. In exceptional cases in which there is a need for equipment that deviates from the standard, a manufacturer could apply for a variance under § 1010.4 (21 CFR 1010.4).

Accompanying the October 1, 1975 draft beam quality amendment was a proposal that would establish a minimum x-radiation exposure rate requirement for dental x-ray systems designed for use with intraoral image receptors. The specific value of 300 milliroentgens (mR) in 2 seconds or less was chosen to provide the capability of making a bitewing radiograph of an adult patient using dental radiographic film of American National Standards Institute Speed Group D in not more than about 3 seconds with dental x-ray equipment that would meet the draft beam quality requirement. Comments received in response to the draft proposal indicated that the minimum exposure rate of 600 mR in 2 seconds or less would seem to be more suitable.

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The FDA is withdrawing the proposed exposure rate requirement because there seems to be no need for it at this time. At present there are no dental x-ray machines being manufactured or imported into the United States that are limited to 50 kVp or less. Therefore, it would appear that certified x-ray systems now being marketed in the United States would meet the minimum exposure rate value of 600 mR in 2 seconds or less while, at the same time, complying with the new beam quality requirement.

REFERENCES

1. Saulnier, V. E. and J. H. Barr, "Compact Foreign-Made X-Ray Generators: An Evaluation of Their Acceptability for Effective Dental Radiography. I. A Review of the Literature," *Oral Surgery, Oral Medicine and Oral Pathology*, 38(5):810-818, November 1974.

2. Lee, W., "Comparative Radiation Doses in Dental Radiography," *Oral Surgery, Oral Medicine and Oral Pathology*, 37(6):962-968, June 1974.

3. Alcox, R. W. and W. R. Jameson, "Patient Exposures from Intraoral Radiographic Examinations," *Journal of the American Dental Association*, 88:568-579, March 1974.

4. National Council on Radiation Protection and Measurements, "Dental X-ray Protection," NCRP Report No. 35, Washington, DC, March 9, 1970; available from NCRP Publications, P.O. Box 4867, Washington, DC 20008.

5. American National Standards Institute, "Dental X-ray Equipment," ANSI MD 156.26, 1975, American National Standards Institute, New York; available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

The FDA carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file in Docket No. 75N-0046 with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 as amended (42 U.S.C. 263f)) and under authority delegated to the Commissioner (21 CFR 5.1(a)(3)), it is proposed that Part 1020 be amended in § 1020.30 by revising paragraph (m)(1) to read as follows:

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§ 1020.30

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[FR Doc. 79-2899 Filed 1-29-79; 8:45 am]

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†8.5 Final Regulation—November 30, 1979

- 44 FR 68822 -

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

[Docket No. 75N-0046]

Diagnostic X-Ray Systems and Their Major Components; Amendments to Performance Standard

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The Food and Drug Administration (FDA) amends the performance standard for diagnostic x-ray systems and their major components to modify the beam quality (half-value layer) provision of the standard for dental x-ray systems designed for use with intraoral image receptors. This amendment will reduce the unnecessary x-radiation exposure to the patient that can result from low voltage, low filtration dental x-ray systems.

EFFECTIVE DATE: December 1, 1980.

FOR FURTHER INFORMATION CONTACT:

Raymond F. Coakley, Jr., Bureau of

Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of January 30, 1979 (44 FR 5908), FDA proposed to amend § 1020.30(m)(1) (21 CFR 1020.30(m)(1)) of the diagnostic x-ray systems performance standard to require that the half-value layer (HVL) of the useful beam of any dental x-ray system intended for use with intraoral image receptors operating at 70 kilovolts peak (kVp) and below be equivalent to at least 1.5 millimeters (mm) of aluminum (Al). The current provisions of the standard allow lower values for the HVL. Interested persons were given until April 30, 1979, to submit comments on the proposal, and comments received as late as May 8, 1979, were considered.

Most of the 11 comments received agreed with the proposed rule's general approach to the reduction of unnecessary reduction of unnecessary radiation exposure. Five comments agreed wholly and three others agreed partially; of the three latter comments, one stated that in certain cases the filtration was too great, and the two others stated that in certain cases the filtration provided by the proposed HVL was still not great enough. Of the three negative comments, two disagreed explicitly with the proposed approach and suggested alternatives, and the third comment disagreed implicitly by questioning the agency's interpretation of data. Among the 11 comments, several raised specific technical issues.

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Among the positive comments, one expressed "basic agreement" with this "positive step"; another called the change "necessary and appropriate." A professional organization characterized the proposed rule as "reasonable" and expected it to contribute to the reduction of unnecessary dose in dental x-ray examinations. A manufacturer commended the "proposed actions"; and a state radiation control agency said that these were "a much needed change that will bear fruit in * * * tremendous dose reduction with no loss in diagnostic information."

Among the negative comments, the chief objection was to the specific HVL. At 70 kVp and below, the proposed change provides for an increase in filtration to improve the beam quality, that is, to increase the proportion of photons useful for dental radiography and to reduce the proportion unnecessarily exposing the patient. Two comments referred to benefits that might be obtained above 70 kVp by decreasing the filtration to improve the beam quality.

The comments and the agency's response are as follows:

1. With respect to the proposed HVL for x-ray beams generated at 70 kVp and below, one comment stated that the change would not achieve the proposed rule's stated objective. The comment argued that the increased filtration required to achieve the HVL of 1.5 mm of Al would make it impossible to produce acceptable radiographs because of lack of x-ray output from the system. Eliminating low kVp radiographs, the comment maintained, would not serve those cases where greater contrast in the image is desired. Another comment from a State radiation control agency stated that the change in HVL falls short of being a reasonable health standard. The comment suggested that the minimum HVL for dental equipment operating at 70 kVp or below should be at least 2.0 mm of Al, and the comment noted that increasing filtration on low kVp dental units sufficient to meet this higher standard had brought that State agency many thanks and no negative feedback.

The dichotomy between these views highlights the problem of reducing patient exposure with minimum loss of available radiographic contrast. The proposed minimum HVL of 1.5 mm of Al equivalent was chosen by FDA as a reasonable compromise value. This value balances entrance dose reduction and available radiographic contrast against excessive exposure time, particularly at x-ray tube potentials below 65 kVp.

The agency's data show that most dental radiographers purchase and use a single unit with fixed kVp and filtration.

One may reasonably conclude that the purchasers obtain usable results within the limited range of available radiographic contrast because they use only this unit for their patients. At the present time, fixed kVp dental x-ray units operating below 60 kVp are not being marketed in the United States; but variable kVp units capable of operating as low as 50 kVp are now being marketed with at least 2.5 mm Al equivalent of fixed total filtration. These marketed units are capable of providing adequate image contrast. The revised standard will not prevent the necessary diagnostic capability. However, to increase the minimum HVL requirement to 2.0 mm of Al equivalent would lengthen exposure times and would further reduce available radiographic contrast. The additional reduction in exposure accomplished by adding still more filtration does not justify these operation penalties.

The existing standard requires a minimum HVL of 1.5 mm of Al at 70 kVp; this HVL is generally achievable with a total filtration of 1.5 mm of Al equivalent at potentials as low as 65 kVp. For conventional single phase self-rectified units, the change in the standard would, in effect, require a total filtration greater than 1.5 mm of Al at potentials below 65 kVp and a total filtration slightly greater than 2.0 mm of Al at 50 kVp. Thus, in practical terms, conventional machines operating below 55 kVp would no longer be effective because of the excessive exposure times required for sufficient radiation output and could not be marketed in the U.S. in the future. The agency concludes, therefore, that the comments do not justify any change from the proposed HVL.

2. Two comments, one from a State radiation control agency and one from a manufacturer, argued for an alternative to improving the beam quality for x-ray beams produced at or below 70 kVp. The comments noted that the required filtration will result in reduced radiation output and concluded that longer exposure times, patient motion, and the inability to use optimum technique factors will produce inferior radiographic images. The second comment also mentioned retakes as a consequence. The two comments recommended that a minimum operating potential of 70 kVp be required for dental x-ray machines, even though this would cause the elimination of some units.

As discussed in paragraph 1 of the preamble to the proposal, the agency intends that dental x-ray systems provide x-ray beam qualities that yield the maximum diagnostic information with the minimum dose to the patient. This objective can be attained at tube potentials below 70 kVp. The agency believes that safe and effective use of dental x-ray machines is possible for systems operating below 70 kVp when these systems meet the new HVL requirement of 1.5 mm of Al. The agency also notes that units operating at low kVp could have increased milliampere (current) capabilities with their consequent increased useful radiation output to avoid longer exposure times with their consequent patient motion unsharpness. The recommendation is therefore rejected.

3. The same State agency and manufacturer also argued in favor of a minimum radiation output level. Another comment suggested that the use of higher output x-ray systems or the development of faster imaging devices should be encouraged because x-ray exposure rate may be of greater importance than has been previously recognized. The comment noted that, because exposure of a posterior periapical film in an adult may require 200 to 300 milliroentgens (mR), exposure times as long as 1 second would be required for systems operating at a minimum rate of 600 mR in 2 seconds. Although the comment does not state the tube potentials or film type being used in that example, it does imply that such exposure times are unacceptable.

As discussed at length in paragraph 6 of the proposal, the agency considered establishing a minimum exposure rate for all dental units to avoid excessive exposure times and motion unsharpness. The American Dental Association (ADA), however, has endorsed a maximum exposure time of 5 seconds for dental x-ray procedures. The agency agrees with the ADA argument that motion unsharpness is not a controlling image quality factor under usual conditions and within that time interval. Minimum system output levels are not required, therefore, under usual conditions to shorten that time interval. The agency will consider taking action if any marketed dental units require exposure times longer than 5 seconds or if further research demonstrates the need for exposure time limits. Such action should not be needed so long as available intraoral radiographic film is no slower than American National Standards Institute Speed Group D.

4. One comment questioned the statement in the preamble to the proposal that suggested that an HVL of 1.5 mm at 50 kVp would be achieved with a total filtration of 2.5 mm of Al equivalent. The comment cited data in a 1968 report of the National Council on Radiation Protection and Measurements (NCRP), Report No. 33 (Ref. 1), which shows an HVL of 1.49 mm of Al equivalent to a total filtration of 2.0 mm of Al. The NCRP data reflect the minimum filtration that, under optimum conditions, can achieve a given HVL. The preamble statement reflected the approximate equivalent filtration that would safely achieve the required HVL of 1.5 mm Al.

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The two are not contradictory. Further, the agency advises that the standard establishes minimum HVL's for given tube potentials. It does not specify the amount of filtration to be used or the means to achieve the necessary HVL. The comment requires no change in the final rule.

5. One comment asked for a further explanation of FDA's rationale for the proposed HVL for x-ray beams generated above 70 kVp. The comment agreed that reduction in the HVL would increase the skin entrance dose, but it pointed out that the integral dose would decrease. This effect, the comment said, could be seen in the data referred to only in part in the preamble to the June 19, 1975 advance notice of proposed rulemaking (40 FR 25830). The comment contended that the totality of the data shows that reduced patient dosages would result from a decrease in filtration at high kVp and asked whether any other data were available that lead the agency to maintain the present HVL requirements for systems operating above 70 kVp. Another comment presented illustrations to show that less filtration would achieve the proposal's objectives. This comment argued that a filter functions to remove from the x-ray beam more of those photons that do not contribute to the formation of an image on the film than those that do contribute, thus reducing the relative amount of needless exposure of the patient. Because an increase in potential increases the relative amount of useful photons as well as the total number of photons (when exposure time, milliamperage, and filtration are being held constant), exposure time can be shortened for high kVp. Therefore, the comment argued, the filtration should not be increased because it will decrease the number of useful photons and increase the total exposure. Instead, filtration should be decreased.

The agency has considered reducing present HVL requirements at high potentials as an approach to allowing more latitude in designing acceptable x-ray equipment. However, too few modern research reports are available to show sufficiently improved imaging quality to justify the somewhat higher entrance doses produced. In addition, several State agencies enforcing present requirements questioned allowing higher entrance doses when dental radiographers seem satisfied with the machines as presently equipped. In the absence of definitive studies showing substantial improvement in imaging quality or reduction in patient exposure from beams or lower HVL at accelerating potentials greater than 70 kVp, the agency concludes that the present standard must be continued.

6. One of the comments misunderstood Table I as published in the proposal and asked why the table showed HVL values less than 1.5 mm Al for tube voltages less than 70 kVp. An-

other comment understood Table I to contain altered filtration requirements for all classes of dental equipment.

FDA included Table I in the proposal only for the convenience of the reader, but it recognizes that the inclusion may have been confusing because the table was identical to Table I in current § 1020.30(m). The table referred to x-ray systems other than those affected by the proposed revision to § 1020.30(m), namely nondental units, dental units designed for use with extraoral image receptors, and dental x-ray units manufactured or assembled before the effective date of this amendment. To clarify the distinction between new dental units designed for use with intraoral image receptors and other diagnostic x-ray systems, § 1020.30(m) has been rewritten and Table I has been restructured. These changes did not alter the meaning of either. The final version of the rule should prevent similar misunderstandings in the future.

7. One comment suggested that FDA encourage the matching of HVL requirements of the x-ray system to the image receptors with which it is to be used. The comment noted that many image receptors have an energy-dependent response and that their use, particularly in special procedures, is most efficient when beam quality matches receptor sensitivity; however, the comment did not identify the special procedures for which this need exists.

The agency has considered the energy dependence and speed of currently used image receptors. Radiographic silver bromide gelatin-emulsion film continues to be essentially the only intraoral image receptor in use. The energy response of this film seems reasonably well matched to the beam quality generated by modern dental x-ray units. Therefore, the agency concludes that the comment does not require any further revision to the standard at this time.

8. One comment noted that the proposal would require beam quality to be evaluated by the voltage applied to the x-ray tube and argued that the need for and the quality of required filtration cannot be evaluated in this manner because HVL and voltage applied to the tube cannot be equated.

Both HVL of the x-ray beam and operating potential of the x-ray tube must be measured under the same conditions. Both the existing and the proposed agency standards for minimum beam quality require that HVL be measured at (not "by") specified kVp because HVL alone is not sufficient to specify beam quality. For compliance testing and premarket certification, manufacturers measure both parameters together. In practice, beam quality also depends on the waveforms of voltage and current. However, a beam generated by a single phase, self-rectified, x-ray machine is assumed for the values stated in the standard. The comment is rejected.

Reference

National Council on Radiation Protection and Measurements, "Medical X-ray and Gamma-Ray Protection for Energies up to 10 MeV—Equipment Design and Use," NCRP Report No. 33, Washington, DC, February 1, 1968; available from NCRP Publications, P.O. Box 30175, Washington, DC. 20014.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 as amended (42 U.S.C. 263f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), 21CFR part 1020 is amended by revising § 1020.30(m)(1) to read as follows:

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§ 1020.30

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[FR Doc. 79-36581 Filed 11-29-79; 8:45 am]

11.—Amendment of Assembly/Reassembly Policy

†11.3 Proposal—April 17, 1979

– 44 FR 22755 –

[Docket No. 76N-0055]

[21 CFR Part 1000]

Diagnostic X-Ray Systems; Proposed Amendment of Assembly and Reassembly Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to revoke the regulation prohibiting the assembly of uncertified components into any diagnostic x-ray system or the reassembly of uncertified components associated with a change of ownership and location that is to become effective on August 1, 1979. A study recently performed by the agency indicates that, although this regulation will affect only a small fraction of the uncertified systems now in use, it may nevertheless have a significant adverse impact on the systems affected in terms of increased cost of x-ray equipment and interruption of health care delivery. The study also indicated that, for the systems affected, the regulation is not likely to be cost effective. Other contemplated or existing programs are more effective and will address the improvement of radiation safety performance of all diagnostic x-ray systems. The agency, therefore, proposes to revoke this regulation and extend the provisions permitting installation of uncertified components into existing systems whose components are all uncertified and the provisions permitting continued reassembly of uncertified equipment indefinitely. The regulation that was designed to aid the transition from the sale of uncertified to certified equipment when the diagnostic x-ray standard became effective on August 1, 1974, is no longer necessary and is also being revoked.

DATES: Comments by May 17, 1979; the proposed effective date of a final rule based on this proposal is the date of publication of the final rule in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Robert Phillips, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION:

History Overview

The Federal performance standard for diagnostic x-ray systems and their major components (§§ 1020.30, 1020.31, and 1020.32 (21 CFR 1020.30, 1020.31, and 1020.32)) was published in the FEDERAL REGISTER of August 15, 1972 (37 FR 16461). This standard contains performance requirements for specified x-ray system components and for diagnostic x-ray systems made up of these components. The standard also contains administrative controls that further ensure the radiation safety of diagnostic x-ray systems. Among these is the requirement that manufacturers certify that all specified components manufactured after August 1, 1974, comply with the standard.

After publication of the August 15, 1972 final rule, manufacturers posed a number of questions on how the standard would apply to the sale and installation of both new and used x-ray components. Questions such as the following were not addressed by the performance standard:

(1) How would the standard apply to components physically produced before the effective date of the standard but assembled into a system after the effective date of the standard?

(2) How should the assembly of uncertified components into a system containing certified components be controlled?

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(3) How should the reassembly, rebuilding, or refurbishing of used x-ray components or systems be controlled?

(4) How should the standard be applied to preserve the radiation safety performance provided by certified components and systems?

(5) How should the standard be applied to encourage the improvement of existing x-ray systems through the addition of certified components?

Because guidance was necessary for manufacturers and users in these situations, two notices of proposed rule-

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making addressing these situations were published in the Federal Register of February 28, 1973 (38 FR 5349). After incorporating changes indicated by comments on the proposals, § 1000.16 (21 CFR 1000.16) was published as a final rule combining these two proposals in the Federal Register of July 29, 1974 (39 FR 27432) and became effective August 1, 1974.

This rule characterized the agency's regulatory policy concerning assembly and reassembly of diagnostic x-ray systems. In the context of this policy, "assembly" refers to the installation of new components for the first time to form a complete x-ray system, and also to the installation of one or more components into an existing system. "Reassembly" refers to the installation of used components from one or more previously existing systems to form a diagnostic x-ray system.

Section 1000.16 provided for a 5-year transition period after the effective date of the standard, during which reassembly of any x-ray system was permitted, and the assembly of uncertified components was permitted as long as no certified component was involved in the system. However, the policy also provided that, after August 1, 1979, no uncertified components could be assembled into a system or reassembled when the reassembly was associated with a change of ownership and location.

The 5-year transition period permitted by § 1000.16 was intended to:

(1) Prevent the downgrading of the radiation safety performance of certified components and systems containing certified components, by requiring that new, complete systems be composed of either all uncertified or all certified components, and by prohibiting replacement of a certified component in an x-ray system by an uncertified component (§ 1000.16(a)(1)).

(2) Promote the upgrading of systems containing uncertified components, by requiring that once a certified component has been installed into a system, all future components installed into the system must be certified (§ 1000.16(a)(2) and (3)).

(3) Allow the reassembly of systems that have been upgraded with one or more certified components (§ 1000.16(a)(4)).

(4) Allow the assembly of new systems containing both uncertified and certified components after the effective date of the standard, provided that all the components had been purchased before the effective date of the standard (§ 1000.16(b)).

After August 1, 1979, § 1000.16 was intended to:

(1) Extend and tighten the provisions of § 1000.16(a) by requiring that all new systems contain only certified components and force the upgrading of uncertified systems when components of these systems are replaced due to wear and tear by requiring that all components added to any system be certified (§ 1000.16(c)).

(2) Prevent the reassembly of uncertified components by allowing only certified components to be reassembled, when a system is sold and relocated (§ 1000.16(d)).

Thus, no uncertified components or systems may be marketed and installed after August 1, 1979, under the current provisions of § 1000.16(c) and (d).

Reevaluation of Assembly and Reassembly Provisions

As part of a program of reevaluating the benefits and economic impact of regulations on diagnostic x-ray systems, FDA has completed a new cost-benefit analysis of the diagnostic x-ray performance standard (§§ 1020.30, 1020.31, and 1020.32) and the policy on assembly and reassembly of components (§ 1000.16). This reevaluation was made, first, to account for the experience gained through the administration of the regulations, and, second, to include data not available when the costs and benefits of the regulations were originally assessed. A draft of this document, "A Second Look at the Costs and Benefits Associated with the Diagnostic X-Ray Equipment Performance Standard and the Policy on Assembly and Reassembly" (Ref. 1), is on file with the Hearing Clerk, Food and Drug Administration (address above), and is available to interested parties upon request. The analysis has resulted in the following conclusions concerning the policies on assembly and reassembly of components and systems:

(1) The provisions of § 1000.16 that are effective after August 1, 1979, will affect only a small fraction of the uncertified x-ray systems currently in use.

(2) The total impact of this regulation, in terms of increased cost for the x-ray equipment or interruption of health care delivery, may be significant.

(3) For those uncertified systems that would be affected, by virtue of their sale and relocation, § 1000.16 is not likely to be a cost-effective approach to improve the radiation safety performance of x-ray systems.

FDA, therefore, believes that the Federal policy concerning used x-ray equipment as it is currently scheduled to be after August 1, 1979, is not appropriate. Controls are needed, however, after August 1, 1979, to preserve the radiation safety provided by certified systems and to promote the continued upgrading of uncertified x-ray systems when it may be done in a constructive, cost-effective manner. Therefore, the agency has examined modifications to § 1000.16 that would establish the desired controls at reasonable cost. A discussion of the proposed modifications follows.

Reassembly of Uncertified X-Ray Equipment

Section 1000.16(d) as currently constituted will prohibit the reassembly of uncertified x-ray components and systems after August 1, 1979, if the reassembly is associated with a change in ownership and location of the components or system. FDA proposes to revoke this section to permit the continued reassembly of uncertified x-ray equipment.

Because both a change in ownership and a relocation of the system are required, the effect of § 1000.16(d) is limited to a small percentage of the total number of x-ray systems. The agency's cost-benefit analysis estimates that, at the end of 1979, there would be about 100,000 uncertified systems in use. The analysis also estimates that 1,100 to 2,600 uncertified systems would be resold and relocated and thus would come under the provisions of § 1000.16(d) in the year following August 1, 1979. This represents an annual rate of 1 to 2 percent of the uncertified systems expected to be in use during that year. Furthermore, approximately 95 percent of these x-ray systems are less than 14 years old. Thus, in the first year after the effective date of § 1000.16(d), the large majority of systems entering the used equipment market will have been manufactured after 1965. These systems contain many of the features required by the Federal performance standard because they generally comply with the standards set out in Report No. 33 of the National Council on Radiation Protection and

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Measurements (Ref. 2). For example, almost all stationary, general-purpose radiographic systems in this group already have beam-limiting devices that permit adjustment of the size of the x-ray field. The older systems that have fixed collimation or no collimation at all, and, therefore, have poor radiation safety performance, will generally not be affected by § 1000.16(d) because they are unlikely to be resold in this country. They are generally among the 6,500 systems that the analysis estimates are removed from service each year because they wear out.

A major factor the agency considered in developing § 1000.16 was the anticipated availability of used certified equipment by August 1, 1979. However, little, if any, certified equipment is now expected to reach the used equipment market by that date. Therefore, users who contemplate or require replacement of a system and who are normally purchasers of used x-ray systems would have to purchase new certified systems at a much higher cost than a used system; forgo the replacement of the system entirely, thereby retaining antiquated equipment in operation; or be forced to curtail or close down x-ray services.

Which of these courses of action would be chosen in individual situations is uncertain. However, to the extent that users retain antiquated equipment or curtail x-ray services, the ability to provide good radiological services would be adversely affected.

The economic impact of the additional cost of purchasing new equipment and the loss in resale value of used equipment under the current regulation has been estimated to be between 34 and 121 million dollars in 1980 and between 18 and 64 million dollars in 1985. Furthermore, the analysis reported a benefit/cost ratio for § 1000.16 after August 1, 1979, of 0.4 to 0.6 and a benefit/cost ratio for the diagnostic x-ray standard of 4.5. Thus, § 1000.16 as currently constituted is only ⅒ as cost effective as the x-ray standard.

FDA notes that cost-benefit analyses of complex issues are usually not exact because all of the necessary data are generally not available. In addition, it is usually necessary to use average and approximate numbers to make the calculations tractable, particularly in this case, in which the benefit—radiation exposure reduction to the population—must be expressed as an economic value. The agency, therefore, believes that a regulatory action should not be based solely on a cost-benefit analysis, although such analysis may be a useful indicator of which of several alternatives should be pursued to achieve a desired result.

Several current or contemplated agency action programs address the improvement in performance of all diagnostic x-ray systems, not just uncertified systems that enter the used equipment market. Although these programs involve voluntary compliance, participation by health care facilities is very high. The programs generally are designed to increase the quality of radiographs and lower radiation exposure. Nationwide programs are currently under way for mammography and dental radiology. In addition a more general facility-based quality assurance program has been started (see the FEDERAL REGISTER of April 28, 1978 (43 FR 18207)). The agency is also working with a task force of the Conference of Radiation Control Program Directors to develop a general quality assurance program to be used by the States. The agency believes that these programs, which tend to reduce radiation exposure, improve image quality, and reduce costs are more cost effective than § 1000.16(d) in improving the performance of uncertified x-ray systems and will reach more such systems, not just those that enter into commerce.

In addition, local controls have become more effective in improving the performance of older x-ray systems. Forty-five States currently have some form of comprehensive radiation protection regulations. Of these, 26 have adopted Part F of the 1970 or 1974 version of the Suggested State Regulations for the Control of Radiation (see the FEDERAL REGISTER of July 15, 1975 (40 FR 29749)). Part F is a model state regulation for diagnostic x-ray equipment. An additional 14 States are in the process of adopting the 1974 or 1978 versions. Five States have some other form of regulation. As more States adopt the model regulation, the radiation safety of older x-ray systems will be improved. The advantage of this local control of uncertified x-ray systems is that improvements will occur whether or not the system is sold and relocated. Thus, the performance of all uncertified x-ray systems can be improved. Under these programs, poorly performing systems are found on a case-by-case basis and additional costs are borne only by owners of such systems, not by owners of systems that perform adequately.

Furthermore, attrition is gradually reducing the availability supply of uncertified components. As uncertified components wear out in older uncertified systems, they will generally be replaced by certified components because of the unavailability of suitable used uncertified components. Moreover, according to a provision of § 1000.16 that FDA does not propose to change, once a certified component enters a system, any further component entering the system must also be certified (§ 1000.16(a)(2)). This process will result in the further upgrading of older x-ray systems.

This proposal to revoke § 1000.16(d) would, therefore, trade the forced upgrading of a small number of uncertified x-ray systems by a non-cost-effective approach for a more gradual upgrading of all uncertified systems by methods that would make more efficient use of resources.

Installation of Uncertified Components

FDA has compared the relative effects of § 1000.16 (a) and (c). Both paragraphs have the same effect, except that § 1000.16(c) prohibits the installation of an uncertified component into any existing system, while § 1000.16(a) allows the installation if all the components of the existing system are uncertified. The agency questions whether the more restrictive prohibition in § 1000.16(c) and its effective date of August 1, 1979, is necessary or desirable.

Replacing a single uncertified component in an uncertified system with a certified component does not provide as much performance improvement as replacing the uncertified component with a group of certified components. For example, the replacement of an uncertified tube-housing assembly by a certified component when the other components of the system are uncertified may not provide the same improvement in radiation protection performance as replacing both the tube-housing assembly and the beam-limiting device.

A related issue was addressed in a final rule published in the FEDERAL REGISTER of November 8, 1977 (42 FR 58167), in which the agency indicated that, for stationary, general-purpose x-ray systems, the additional cost of a beam-limiting device providing positive beam limitation (PBL) is not always justified for older systems when the PBL device is added to the x-ray system as a replacement for the original beam-limiting device. Therefore, the regulation requires that stationary, general-purpose x-ray systems be equipped with beam-limiting devices providing PBL only if the system also contains a tube-housing assembly, x-ray control, and, for those systems so equipped, an x-ray table, all of which have been certified under § 1020.30.

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In another action (see the FEDERAL REGISTER of February 24, 1978 (43 FR 7654)), FDA proposed to formalize in the regulations the existing policies for repairing systems. Recognizing that repair by exchange of identical components minimizes service interruption and allows more efficient repair at locations other than at the site where the component is used, the FDA policies had allowed, independently of § 1000.16(a), (c), and (d), the installation of specified components into an x-ray system on an exchange basis when an identical model is installed in place of a malfunctioning component. No substantive negative comments were received regarding this proposal.

The agency believes that these two actions have minimized the differences between § 1000.16(a) and § 1000.16(c). In place of § 1000.16(c) and (d), FDA proposes to remove the August 1, 1979 expiration date from § 1000.16(a), which is currently in effect and which is understood by the radiological community. The agency believes § 1000.16(a) has established the controls necessary to protect the integrity of certified equipment and to promote the upgrading of systems containing uncertified components.

Public Participation

On September 1, 1978, a summary of the cost-benefit analysis and the rationale for the action proposed in this notice was distributed to interested manufacturers, dealers, assemblers, and members of the general public to allow early public participation in the development of the proposed amendment. FDA received more than 50 comments, most of which favored changing the policy concerning the reassembly of x-ray components. Several manufacturers, however, urged that no change should take place.

Many of the comments suggested that certain variables in the cost-benefit analysis had been estimated incorrectly because the cost-benefit analysis used average values in some cases.

The agency recognizes that although use of average values in conducting a cost-benefit analysis is imprecise, a sensitivity analysis has shown that it is unlikely that the major cost-benefit conclusions are incorrect. Furthermore, the cost-benefit analysis is not the sole basis for this proposal. It has, however, been used to indicate how this proposed agency action would be more appropriate than other possibilities.

Another group of comments indicated that dealers and manufacturers may have already made investments and marketing plans in contemplation of the August 1, 1979, effective date. Changing the regulation at this point could result in an economic loss.

FDA believes that the adverse economic consequences of allowing § 1000.16(c) and (d) to become effective as scheduled would be far greater than those resulting from its elimination.

The documents distributed for public comment, together with the comments received, are on file with the Hearing Clerk, Food and Drug Administration.

Under section 358(f) of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f), a draft of this proposal and a summary of comments received were presented to the Technical Electronic Product Radiation Safety Standards Committee for its review at its 17th meeting on November 9, 1978. This Committee is a permanent statutory advisory committee to the Secretary of Health, Education, and Welfare, that must be consulted before establishment or amendment of performance standards for electronic products. At this meeting, the Committee did not concur with the Bureau's position concerning amending § 1000.16. FDA's Bureau of Radiological Health communicated with the Committee by letter on December 11, 1978, and presented a revised proposal and reviewed the Bureau's position. A majority of the Committee has since concurred with issuing this revised proposal for public comment.

Inventories of Uncertified Components

FDA has also reviewed § 1000.16(b), which was intended to minimize the economic impact incurred by manufacturers and assemblers because of their inventories of uncertified components that, under § 1000.16(a), could not be assembled together with certified components after August 1, 1974. It is unlikely, after 5 years, that there is a significant number of new systems, composed of both certified and uncertified components, that were purchased before August 1, 1974, but not yet assembled. The agency has therefore determined that § 1000.16(b) is no longer needed in the regulations.

Other Actions Pending

In another proposal (see the FEDERAL REGISTER of February 24, 1978 (43 FR 7654)), FDA proposed to recodify § 1000.16 by removing it from 21 CFR Part 1000, Subpart B—Statements of Policy and Interpretation, and placing it into 21 CFR Part 1020—Performance Standards for Ionizing Radiation Emitting Products, where it would be designated § 1020.30(p). This proposal was made to identify these policies and interpretations more clearly as additions to or clarifications of the specific requirements of the performance standard. The February 1978 proposal would also amend the provisions currently codified in § 1000.16(a)(4) to clarify the fact that replacement of components during reassembly of an existing x-ray system is permitted, and revoke § 1000.16(e) because it duplicates the requirements of § 1020.30(d). The agency anticipates that the February 1978 proposal and the current proposal will be combined into a single final rule because no substantive comments were received on the earlier proposal concerning recodification.

Proposed effective date: FDA proposes that these amendments become effective on the date of publication of the final rule in the FEDERAL REGISTER. This early effective date is necessary because the parts of the regulations that this amendment would repeal will become effective on August 1, 1979.

References

The following references are on file with the Hearing Clerk, FDA (address below) and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

(1) Bureau of Radiological Health, FDA, "A Second Look at the Costs and Benefits Associated With the Diagnostic X-Ray Equipment Performance Standard and the Policy on Assembly and Reassembly, Draft No. 3," Rockville, MD, 1979.

(2) National Council on Radiation Protection and Measurements, "Medical X-Ray and Gamma Ray Protection for Energies up

to 10 MeV," Report No. 33, Washington, DC, 1968.

The agency has carefully considered the environmental effects of the proposed regulations, and because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety 82 Stat. 1177-1179 as amended (42 U.S.C. 263f)) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 1000 be amended in § 1000.16 by revising the introductory text of paragraph (a), revising paragraph (a)(4), and deleting and reserving paragraphs (b), (c), and (d) as follows:

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§ 1000.16

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[FR Doc. 79-11677 Filed 4-16-79; 8:45 am]

†11.4 Final Regulation—July 31, 1979

- 44 FR 44843 -

PART 1000—GENERAL

[Docket No. 76N-0055]

Diagnostic X-ray Systems Assembly and Reassembly; Suspension of Regulation

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The Food and Drug Administration (FDA) is amending 21 CFR 1000.16 by suspending those provisions of the regulation that would have, effective August 1, 1979, prohibited (1) the assembly of uncertified components into any diagnostic x-ray system or (2) the reassembly of uncertified components associated with a change of ownership and location. The agency continues indefinitely the provisions permitting installation of uncertified components into existing systems whose components are all uncertified and the provisions permitting continued reassembly of uncertified equipment. This action is taken because the agency is considering the need to amend the assembly/reassembly regulation but cannot publish an amendment before the August 1, 1979, changes take effect.

EFFECTIVE DATE: July 31, 1979.

FOR FURTHER INFORMATION CONTACT:

Robert Phillips, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: Section 1000.16 (21 CFR 1000.16) became effective August 1, 1974, but provided for a 5-year transition period during which reassembly of any system containing components not certified under the performance standard for diagnostic x-ray systems and their major components was permitted, as was the assembly of uncertified components into existing systems so long as no certified component was involved in the system. However, the regulation also provided that, after August 1, 1979, no uncertified components could be assembled into a system or reassembled when the reassembly was associated with a change of ownership and location.

In the Federal Register of April 17, 1979 (44 FR 22755), FDA proposed to revoke the provisions of § 1000.16 that apply to assemblies which take place after August 1, 1979, and to extend indefinitely the transitional provisions, because other contemplated or existing agency programs would better improve the radiation safety performance of all diagnostic x-ray systems without reducing health care delivery.

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The agency is currently reviewing the comments it received on the April 17 proposal. It will, however, be unable to complete its review in time to publish a final rule responsive to the comments before August 1, 1979. FDA is, therefore, continuing until further notice § 1000.16 (a) and (b), and suspending until further notice § 1000.16 (c) and (d).

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), 21 CFR Subchapter J is amended in Part 1000 by continuing § 1000.16 (a) and (b) in effect until further notice and by suspending § 1000.16(c) and (d) until further notice.

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[FR Doc 79-23642 Filed 7-27-79; 11:29 am]

†11.5 Final Regulation—August 24, 1979

– 44 FR 49667 –

PART 1000—GENERAL

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

[Docket No. 76N-0055]

Diagnostic X-Ray Systems; Amendment of Assembly and Reassembly Provision and Performance Standard

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations on assembly and reassembly of diagnostic x-ray systems by revoking the provision prohibiting the assembly of uncertified components into any diagnostic x-ray system or the reassembly of uncertified components associated with a change of ownership and location that was to have become effective on August 1, 1979. The agency is extending indefinitely the provisions permitting installation of uncertified components into existing systems whose components are all uncertified and the provisions permitting continued reassembly of uncertified equipment. Furthermore, the revised policy is recodified as an integral part of the performance standard for diagnostic x-ray systems. The agency is also incorporating into the performance standard for diagnostic x-ray systems clarifying interpretations concerning (1) the reporting of assembly of accessory components, (2) the reloading of x-ray tube-housing assemblies, and (3) the modification of certified diagnostic x-ray components and systems that have been made by the agency since promulgation of the standard.

EFFECTIVE DATE: September 24, 1979.

FOR FURTHER INFORMATION CONTACT:

Robert Phillips, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: This amendment combines two proposals that were published in the FEDERAL REGISTERS of February 24, 1978 (43 FR 7654) and April 17, 1979 (44 FR 22755).

Amendment of Policy on Assembly and Reassembly

In the FEDERAL REGISTER of April 17, 1979 (44 FR 22755) FDA proposed to amend 21 CFR 1000.16, which identifies the agency's policy on assembly and reassembly of diagnostic x-ray systems. This document proposed to: (1) revoke the regulation prohibiting the assembly of uncertified components into any diagnostic x-ray system (21 CFR 1000.16(c)) and the reassembly of uncertified components associated with a change in ownership and location (21 CFR 1000.16(d)), both of which would otherwise have become effective on August 1, 1979; and (2) to extend indefinitely the provisions of 21 CFR 1000.16(a), which identify the conditions under which certified and uncertified components may be assembled and reassembled together. The agency at the same time proposed to revoke 21 CFR 1000.16(b), originally designed to aid the transition from the sale of uncertified to certified equipment when the diagnostic x-ray standard became effective on August 1, 1974, because the section would no longer have been necessary.

Twenty-two comments were received on the proposal within the 30-day comment period. Of these, seven were submitted by dealers or assemblers of x-ray equipment, one by a manufacturer, one by a national dealer's organization, five by physicians, two by national medical organizations, four by hospitals and two by private individuals. The agency was unable to complete its review of the comments in time to publish this final rule before August 1, 1979. Thus, in the FEDERAL REGISTER of July 31, 1979 (44 FR 44843), FDA continued until further notice § 1000.16(a) and (b), and suspended until further notice § 1000.16(c) and (d). This final rule constitutes the further notice anticipated by the July 31 document.

1. Many comments expressed opinions or concerns that were apparently based on a misunderstanding of the existing regulation or the April 17 proposal. For example, several comments expressed concern that the proposed change would allow uncertified components to be installed with certified components, resulting in poorer radiation protection for patients and users.

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The agency advises that under § 1000.16(a), uncertified components can only be installed into a system if the system is composed entirely of uncertified components. Once a system contains one or more certified components, then every component added to that system must also be certified. A reassembled system can contain both certified and uncertified components if they were all part of the previously existing system. However, if this reassembled system contains one or more certified components, then any component added to the system that was not part of the original system prior to reassembly must also be certified. The integrity of certified equipment is, therefore, protected.

2. Three comments expressed the concern that poorly manufactured equipment, substandard design, or substandard performance of older equipment contributed to unnecessary radiation exposure of the public and that the object of the policy on assembly and reassembly was to reduce this unnecessary radiation exposure by eliminating substandard systems.

The agency agrees that the purpose of the performance standard and the policy on assembly and reassembly is to reduce unnecessary radiation exposure to the public. A study performed by the agency and discussed at length in the April proposal, however, has shown that the policy as it would have applied after August 1, 1979, is not an effective means of removing substandard equipment from use. This is because § 1000.16(c) and (d) will impact within a reasonable time on only a small portion of the systems that provide substandard performance while preventing the sale and continued use of adequate systems because they lack certification.

The agency believes that a substandard radiograph is not necessarily the result of using an older machine. There are older machines that have been maintained so that they perform reliably and possess acceptable radiation protection. Other older machines and some newer ones which have not been well maintained do not perform reliably. Yet some older machines, owing to their design, cannot be brought to acceptable levels of performance. FDA agrees that these substandard machines should be removed from service. This goal, however, is not achieved by § 1000.16(d) because the system must both change ownership and location for the prohibition to take effect. Under current § 1000.16, substandard machines can remain in use and continue to produce unacceptable films. The agency is convinced that substandard systems are more effectively removed from service or improved by the States under existing inspection programs and radiation safety regulations. However, to further this process, the agency is instituting action programs that assess the performance of various types of x-ray systems. These programs, as described in the proposal, are better suited to improving the performance of x-ray equipment than is § 1000.16(d). Thus, the agency concludes that the comments do not warrant withdrawal of the proposal.

3. Two comments interpreted FDA to have stated that 95 percent of all x-ray equipment is less than 15 years old. This was a misunderstanding of the agency's description of the used equipment market. The agency actually stated that 95 percent of equipment reaching the used market is less than 15 years old.

4. Another comment indicated that there are substantial numbers of outdated portable and mobile systems in use and objected to withdrawal of § 1000.16(d) arguing that the regulation, if continued in effect, would force the retirement of these systems.

This is not a correct interpretation of the regulation. For § 1000.16(d) to apply to the reassembly of a system, the system must both change ownership and be reassembled as part of a change in location. Both the act of manufacture and the introduction into commerce must occur for this restrictive provision to apply. Because a mobile or portable machine does not usually undergo reassembly as part of a change in location, § 1000.16(d) would not apply. The comment is rejected.

5. A comment similar to that in paragraph 4 was based on the assumption that systems containing uncertified components could not be used after August 1, 1979.

This, too, is an incorrect interpretation of § 1000.16. Section 1000.16(d) prevents the reassembly of uncertified components when associated with a change in ownership and location after August 1, 1979. It does not prohibit the continued use of uncertified components or systems containing them after that date.

6. One comment agreed with the agency's proposal but added that it is unfortunate that the regulation does not allow the upgrading of a system when it is resold and reassembled.

The agency advises that the intent of the regulation is to permit the improvement and upgrading of x-ray equipment. The policy on assembly and reassembly as represented by § 1000.16(a) (redesignated in this final rule as § 1020.30(p)) is intended to prevent the downgrading of systems composed of or containing certified components. It does not prevent the upgrading of uncertified x-ray systems with certified components but, in fact, encourages such procedures.

7. Two comments expressed concern that inadequate uncertified beam-limiting devices could not be replaced by more adequate beam-limiting devices as part of the reassembly of a system containing certified components without a positive beam limitation (PBL) type of beam limiting device being installed. In certain cases, PBL is incompatible with the existing system or represents an excessive cost, thereby inhibiting the assembler from improving the beam-limiting device in the system.

The FDA addressed this issue in a final rule published in the FEDERAL REGISTER of November 8, 1977 (42 FR 58167), in which the agency concluded that, for stationary, general-purpose x-ray systems, the additional cost of a beam-limiting device providing PBL is not always justified for older systems when the PBL device is added to the x-ray system as a replacement for the original beam-limiting device. Therefore, 21 CFR 1020.31(e)(2) was revised to require that stationary, general-purpose x-ray systems be equipped with beam-limiting devices providing PBL only if the system also contains a tube-housing assembly, x-ray control, and, for those systems so equipped, an x-ray table all of which have been certified under § 1020.30 (21 CFR 1020.30). Thus, final rule amending § 1000.16 does not affect the provisions of § 1020.31(e)(2). Therefore, the comments are rejected.

8. One comment supported the proposal because § 1000.16(d) prevents a person from moving satisfactorily functioning x-ray equipment within an institution (e.g., moving old equipment from heavy use areas to areas of limited use).

This again is a misunderstanding of the applicability of § 1000.16(d). As indicated in response to comment 4, the condition for the application of § 1000.16(d) is reassembly associated with both a change in ownership and location. Moving a piece of equipment within an institution would only meet one of these tests—relocation. Because the ownership of the equipment would not change, the prohibitions of § 1000.16(d) would not apply. Independent of § 1000.16(d), however, such a relocation will have to conform to the provisions of § 1000.16(a) concerning mixing certified and uncertified components.

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9. One comment objected to the proposal, arguing that there are many manufacturers of good quality and reasonably priced x-ray parts that meet FDA performance standards. Therefore, these facts should mean that limiting the reassembly of uncertified x-ray components would have a small impact on x-ray efficacy and user safety.

FDA in its proposal attributed the adverse impact of § 1000.16 (c) and (d) to two factors: the loss of resale value to a user and the difference between the cost of purchasing a new system and that of purchasing an equivalent used system. The agency is aware of instances where a new low-priced x-ray system might not be as suitable to a user as a more complex used system purchased for the same amount of money. A used system may have been built to withstand heavier use and would undoubtedly contain features not found in new low-cost systems that are similar in price to the used system. Although the equipment may, for many reasons, no longer meet the needs of the original purchaser, a second owner (e.g., a small hospital) might like some of its features and heavy duty construction. Therefore, the comment is rejected.

10. Six comments expressed the opinion that the proposed revocation of § 1000.16 (c) and (d) would assist hospitals and medical facilities in their efforts to contain increasing costs.

FDA recognizes this likelihood and used this argument in the proposal.

11. One comment argued that it will be difficult to ensure that some assemblers do not collect and mix used, certified, and uncertified components to reassemble and sell them as previously existing systems.

The agency is aware of this possibility of abuse but believes it does not justify any change in the proposal. If the question arises as to the origin of a component in a reassembled system containing any certified components, the assembler must be able to document the fact that the components were part of the original system before reassembly.

12. Three comments indicated that the April 17 proposal was inconsistent with previous FDA policy.

The agency agrees that the April 17 proposal represents a policy that differs from the conclusions it came to in 1974 that led to publishing § 1000.16 (see FEDERAL REGISTER of July 29, 1974 (39 FR 27432)). Indeed, the preamble to the April 17 proposal clearly stated that, on reevaluation, the policy concerning used x-ray equipment "is not appropriate." FDA often reevaluates the costs and benefits of its regulations. The reevaluation of § 1000.16 was made to consider experience gained through the administration of the regulations and to consider data not available when the regulations were originally promulgated. The reanalysis led the agency to conclude that only a small fraction of the uncertified x-ray systems now in use would be affected by the regulation. Further, in terms of increased cost of x-ray equipment or interruption of health care delivery, the impact of subsections (c) and (d) may have been significant. Finally, for uncertified systems that would be affected, by virtue of their sale and relocation, § 1000.16 as scheduled to take effect would not likely have been a cost-effective approach to improving the radiation safety performance of x-ray systems.

The agency believes that it is FDA's responsibility to change regulations that are shown to be ineffective or that do not perform the function for which they were designed and, therefore, proposed revoking § 1000.16 (c) and (d). The comment presented no data to dispute the conclusions leading to the proposal and is rejected.

13. Three comments stated that dealers had invested significant amounts of time, manpower, and money training personnel and purchasing test equipment in contemplation of § 1000.16 (c) and (d) becoming effective. Changing the regulation would waste this investment.

FDA disagrees with this argument and rejects the comments. The upgrading of technical expertise, purchasing of test equipment, and training of personnel to ensure that new equipment is assembled and performs properly are benefits to the public. The fact that a system is used and is being reassembled and, therefore, might not be covered by the standard does not mean that it too should not be reassembled to operate at the highest level of performance. The improvement of a dealer's expertise and capability is, therefore, no more than what a conscientious dealer should do to provide a high level of service to customers.

14. One comment indicated that manufacturers and dealers have made production decisions and formulated marketing strategies based on the situation that would exist after August 1, 1979. A change now would cause economic loss.

FDA is aware that the change in § 1000.16(c) and (d) will necessitate changes in production plans and marketing strategies. The agency believes, however, that the possible adverse economic consequences to the public and health care system from allowing §1000.16(c) and (d) to become effective as scheduled would be far greater than those that would result from its elimination. Therefore, it rejects the comment.

15. One comment indicated that the decision to propose the amendment was hasty and is being initiated at the last minute.

FDA notes that, beginning in 1977, the agency, as a result of data then available from experience in enforcement of the standard, became aware of possible adverse consequences resulting from the policy on assembly and reassembly that were unforeseen when § 1000.16 was originally promulgated in 1974. As a result, the Bureau of Radiological Health, on September 1, 1978, unofficially proposed and solicited comments on possible changes in FDA policy. The proposal, along with the comments received, was then presented to the Bureau's advisory committee, TEPRSSC, at its 17th meeting on November 9, 1978. At the meeting, the Committee was not convinced of the correctness of the Bureau's proposed actions and recommended a 1-year delay in the effective date of §1000.16(c) and (d), during which the problem would be further evaluated. In a response to a letter in December 1978, which clarified the Bureau's reasons for the proposal, a majority of the Committee concurred that action be initiated without the 1-year delay previously recommended. Therefore, this proposal has not been developed at the last minute and has afforded several opportunities for widespread public awareness and comment. The agency also believes that, once the question of changing the policy on assembly and reassembly has been publicly raised, a prompt considered decision concerning the proposal is in the public interest.

16. One comment provided a detailed critique of FDA's cost-benefit analysis. With respect to § 1000.16(d), the comment pointed out several possible errors. If values corrected according to the party's claim were substituted into the analysis, the cost of § 1000.16(d) would decrease. The resulting cost-benefit ratio would be closer to 1.0 instead of the 0.4 to 0.6 calculated by FDA. The comment further claimed that the magnitude of the adverse cost impact "would run about ⅓ of the values used by FDA." The adjusted values would result in a maximum adverse cost of $45 million rather than $121 million in 1980 and $22 million rather than $64 million in 1985.

This alternative cost-benefit analysis caused the agency to reexamine its proposal. FDA has concluded, however, that, if the altered analysis were correct, FDA's initial conclusions would still not change: a significant adverse impact on health care delivery would result from the regulation. Also, considering the variability in the factors that must be used in any cost-benefit analysis, the agency believes that a cost-benefit ratio near 1.0 cannot demonstrate cost effectiveness. Cost-benefit analyses of complex issues are usually not exact because all necessary data are seldom available. Therefore average and ap-

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proximate values must often be used to make the calculations tractable. The calculations here were particularly inexact because the benefit (radiation exposure reduction to the population) had to be expressed as an economic value. The benefit of this kind of regulatory action should significantly exceed the cost before it is undertaken. Section 1000.16 did not represent action which promised to show such a very favorable ratio.

Assembly of Systems Purchased Prior to August 1, 1974

17. Two comments indicated that § 1000.16(b), concerning the assembly of systems containing both certified and noncertified components purchased prior to the effective date of the policy (August 1, 1974), should not be eliminated because the respondents had equipment waiting to be installed that was affected by this section.

FDA, in proposing to remove § 1000.16(b), believed that it was unlikely that after 5 years there would be many new systems composed of both certified and uncertified components purchased prior to August 1, 1974, and still awaiting assembly. The comments, however, indicate that there are still some unassembled systems that are exempted by the regulation. If §1000.16(b) were revoked, the owners of these systems would be prohibited from installing them unless they applied for and were granted a variance or exemption from the standard. The original intent of the provision was to permit the assembly of uncertified components purchased before August 1, 1974. Also, § 1000.16(a) permits the reassembly of systems containing both certified and noncertified components. The agency believes that prohibiting assembly of the few systems affected by § 1000.16(b) is an unnecessary economic burden; therefore, the agency is extending §1000.16(b) (redesignated as 21 CFR 1020.30 (p)(2)).

Clarification of Standard and Policies

In the Federal Register of February 24, 1978 (43 FR 7654), FDA proposed to amend the performance standard for diagnostic x-ray systems and their major components (21 CFR 1020.30). This related action was intended to incorporate into the regulation clarifying interpretations and policies that had been made since the promulgation of the standard. Topics addressed were: (1) reporting of assembly of accessory components, (2) reloading of x-ray tube-housing assemblies, (3) recodification of § 1000.16, and (4) modification of certified diagnostic x-ray components and systems.

Three comments were received during the 60-day comment period, one each from a manufacturer, a national manufacturer's organization, and a private individual. All three comments agreed with the agency's proposed amendments.

18. One comment suggested changes in language to clarify the intent of the amendments. This comment argued that in § 1020.30(b)(3) and (q)(2) the phrase, "provide professional or commercial services," can be interpreted to mean something other than medical diagnostic usage of x-ray systems and could result in confusion as to intent. The comment suggests that the phrase be changed to read "for diagnosis or visualization of human beings."

The agency disagrees with this comment. Section 1020.30 applies in its entirety to diagnostic x-ray systems and their major components. Section 1020.30(b)(12) defines any diagnostic x-ray system to mean, "an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization." Section 1020.30(q)(2) includes the term "diagnostic x-ray system" as part of its construction; therefore, the agency concludes that the meaning is clear. Section 1020.30(b)(3), however, uses the term "x-ray system." Although the agency believes the definition is adequate, to clarify the definition further, the word "diagnostic" is added to the first sentence of § 1020.30(b)(3) so that the reference will clearly be to "diagnostic x-ray system."

19. The same comment also addressed the modification of certified diagnostic x-ray components and systems by the owner (§ 1020.30(q)(2)). This proposed new paragraph would permit the owner of an x-ray system

to modify it, provided that the modification did not result in the failure of the component or system to comply with applicable requirements. The proposal would also exempt the owner from submitting reports otherwise required by subpart B of 21 CFR Part 1002. The comment notes that this proposal would not provide for recording of modifications, resulting in problems for the manufacturer, service personnel, and FDA in determining the modification history of any component or system.

The agency agrees with this comment and inserts the phrase "the owner records the date and the details of the modification, and" between the words "provided" and "the" in § 1020.30(q)(2). This addition will require the owner of any system or component to maintain a history of modifications, thereby allowing service personnel and other interested parties to determine what changes or modifications have been made to any system or component.

To clarify FDA's position on the modification of certified x-ray components or systems, the agency advises that § 1020.30(q)(1) prohibits those modifications that will result in noncompliance with a specific performance requirement stated in the performance standard. For example, proper collimator sizing, source-image receptor distance (SID) indication, reproducibility, linearity, etc., may not be modified unless a variance or exemption has been granted.

By contrast, modifications that result in a change to the required information in § 1020.30 (g) or (h) or that change any of the preselected technique factors are not considered modifications to specific performance requirements and are, therefore, permitted under § 1020.30(q)(2). When modifications that invalidate a manufacturer's specification are made, that specification no longer applies. Any permitted modification made at time of installation of a certified component should be documented in the comments section of Form FD-2579 (the form used by an assembler to report compliance with assembly instructions). Modifications made at a later date should be documented as to date and the nature of the modification in the service statement provided by the servicing organization or documented and retained by the user in the service record if such modification is made by the user.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263(f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Subchapter J of Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

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§ 1000.16

§ 1020.30

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[FR Doc. 79-26612 Filed 8-23-79; 8:45 am]

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†13.—X-Ray Beam Limitation Devices for Radiographic and Fluoroscopic X-Ray Systems

†13.1 Proposal—May 9, 1978

- 43 FR 19879 -

[21 CFR Part 1020]

[Docket No. 77N-0061]

DIAGNOSTIC X-RAY SYSTEMS AND THEIR MAJOR COMPONENTS

X-Ray Beam Limitation Devices for Radiographic and Fluoroscopic X-Ray Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: This document proposes amendments to: (1) clarify the X-ray beam limitation requirements for stationary, general-purpose X-ray systems; (2) incorporate interpretations that have been made about the performance of these systems; (3) relax certain requirements for field size adjustments; and (4) permit a capability for overriding the automatic X-ray field size adjustment on spot film and fluoroscopic X-ray systems, if appro-

priate labeling is provided. This document follows from a previous notice of intent.

DATE: Comments by July 10, 1978.

ADDRESS: Written comments to Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Harvey Rudolph, Bureau of Radiological Health (HFX-460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1960.

SUPPLEMENTARY INFORMATION: Under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.), the Commissioner of Food and Drugs proposes to amend the performance standard for diagnostic X-ray systems and their major components (21 CFR 1020.30, 1020.31, and 1020.32). The amendments would modify the requirements of § 1020.31(e)(2) concerning the manner in which means to limit the X-ray field are provided for stationary, general-purpose radiographic systems. The amendments also address §§ 1020.31(g) and 1020.32(b), by permitting a capability for overriding the automatic X-ray field size adjustment on spot film and fluoroscopic X-ray systems and requiring appropriate labels for these override controls when such a capability is provided.

The development of these amendments was announced in a notice of intent published in the Federal Register of April 1, 1977 (42 FR 17494), and drafts of the proposed amendments have been made available for review and comment by interested parties. Under section 358(f) of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f(f)), these proposals have been reviewed by the Technical Electronic Product Radiation Safety Standards Committee, a permanent statutory advisory committee to the Secretary, Department of Health, Education, and Welfare, which must be consulted before establishment or amendment of performance standards for electronic products. The committee concurred with issuing the proposals for public comment. A discussion of the proposed amendments follows.

Revision of Requirement for Positive Beam Limitation

The positive beam limitation (PBL) requirements of the diagnostic X-ray equipment performance standard are currently in § 1020.31(e)(2) (21 CFR 1020.31(e)(2)). It states that all stationary, general-purpose radiographic systems must have means to prevent X-ray exposure until the operator or the system causes the X-ray field to be adjusted to the size of the image receptor. The meaning and intent of this requirement and the methods of complying with it have been subject to misinterpretation; therefore, the agency has issued advisory opinions and compliance policy statements to clarify the PBL requirement for manufacturers and to assist in determining compliance with the standard. Since promulgation of the standard, experience indicates that modifications and additions to the regulations on PBL are necessary for full benefit of this feature and for permitting simplification of the design of these systems. The proposed amendments would revise § 1020.31(e)(2) and establish new § 1020.31(e) (3), (4), and (5). The changes to these requirements are as follows:

1. *Requirement for field size adjustment.* Under the proposed amendments, revised § 1020.31(e)(2) would continue to state the requirement for PBL, but would require adjustment of the size of the X-ray field to the size of the image receptor only if the X-ray field is larger than the image receptor. The current standard requires that the X-ray field be adjusted to the same size as the image receptor each time the image receptor is changed, including when the X-ray field is smaller than the image receptor.

The PBL requirement was established as a means of fostering good radiologic practice and preventing the use, during routine examinations, of X-ray fields that exceed the size of the image receptor and subject the patient to unnecessary radiation exposure. The current provisions of

§ 1020.31(e)(2) permit adjustment of the X-ray field to a size smaller than the image receptor; however, during routine operation of the X-ray system, the X-ray field is first required to be adjusted to the same size as the image receptor to within the tolerances specified in § 1020.31(e)(2)(ii). This requirement was established to prevent the loss of needed diagnostic information, which could lead to repeat examinations if the X-ray field were left at a size significantly smaller than the selected image receptor. During the development of the standard, it was also thought that the lack of a minimum tolerance on the X-ray field size might lead to X-ray films with excessive unexposed margins because of careless or improper adjustment of beam-limiting devices. It was expected that such large unexposed margins could lead to loss of diagnostic information and could result in the use of the next larger film size to avoid the loss of information. The use of larger film sizes would result in increased patient exposure.

The agency has received both formal and informal criticisms from radiologists, radiologic technologists, and others concerning the impact of the requirement that the X-ray field be increased to the full size of the image receptor upon each change of the image receptor. These criticisms cite the inconvenience resulting from this requirement in two circumstances.

The current requirement for agreement of the X-ray field and image receptor dimensions to within 3 percent of the source-to-image-receptor distance (SID) makes it difficult for beam-limiting devices providing PBL to be adjusted so that they provide an unexposed border on the image receptor and also remain in compliance with the performance standard. An increasing number of institutions, as well as radiation control agencies, are adopting requirements that evidence of proper X-ray field limitation shall appear on each radiograph. This is a method of controlling unnecessary exposure resulting from the use of X-ray fields that exceed the size necessary to fully expose the image receptor.

An additional criticism of the current requirement is that this provision inconveniences the user who wishes to make a series of radiographs with the X-ray field smaller than the film. Currently, when such a series of radiographs is being made, the operator often needs to manually adjust the beam limitation device to obtain the smaller field before each exposure instead of adjusting the X-ray field size to the area of interest initially and leaving it unchanged. Thus, one of the attractive features of automatic beam limitation, the elimination of the need for manual adjustment, is lost in this instance. Some systems have incorporated a feature to permit this reduction automatically, but the fact that this performance is acceptable is not clear from the present wording of § 1020.31(e)(2). Even these systems cause the reduced X-ray field to be enlarged to the size of the image receptor and then reduced again upon each change of the image receptor. Such performance is unnecessarily complicated, and the proposed amendment would permit a simplification of these systems.

These problems would be eliminated by revising § 1020.31(e)(2) to require that the dimensions of the X-ray field not exceed those of the image receptor by more than 3 percent of the SID. The PBL system would be required to meet this criterion for any SID for which it is designed. In addition, any amount of undersizing of the X-ray field in comparison with the image receptor would be permitted, thus making the requirement for beam limitation devices providing PBL more consistent with the requirement for spot-film collimation devices. (See FEDERAL REGISTER of June 11, 1975 (40 FR 24909) and February 25, 1977 (42 FR 10983) concerning the spot-film device performance requirements.) If the PBL device permits preselection of a size less than the full image receptor, means to align the X-ray field with the preselected portion of the image receptor would be required.

In addition, such a change would permit PBL to be adjusted to provide an unexposed border on the image receptor and still comply with the performance standard. With the current requirement of § 1020.31(e)(2)(ii), it is difficult to provide such an unexposed margin at all SID's and maintain compliance with the standard. The current situation thus makes enforcement of such a policy or regulation difficult in institutions having both certified and uncertified X-ray systems. The proposed amendment would assist this effort to reduce unnecessary exposure.

This proposal has one disadvantage in that some retakes may be necessary if the system is designed so that the operator needs to manually adjust the beam-limiting device to obtain a larger field when changing to a larger image receptor size and the operator neglects to do so. But this situation should rarely occur once the operator is familiar with the function of the system.

During the development of this proposal, a comment suggested that the inside tolerance on the X-ray field size be maintained, but that it be increased to 6 percent of the SID so that an unexposed border on the image receptor would be possible. It also suggested that adjustment of the X-ray field to the size of the image receptor continue to be required when the X-ray field is smaller than the image receptor size. The arguments in support of this suggestion were similar to those used to support the original PBL requirements.

The Commissioner acknowledges that this suggestion would eliminate the problem facing some X-ray facilities, i.e., providing unexposed borders while still maintaining their equipment in compliance with the performance standard. But, he notes that most users would still be unable to take a series of radiographs with the X-ray beam collimated to the area of interest without manually adjusting the beam-limiting device before each exposure. He also notes that the removal of the inner tolerance would allow manufacturers the option of designing less complex beam-limiting devices. Such devices could be less expensive to buy and maintain. Therefore, the Commissioner has not accepted the suggestion in proposing these amendments, but invites comments on this alternate approach, as well as on the proposed amendment.

2. *Conditions for positive beam limitation.* It is proposed to provide, in a new § 1020.31(e)(3), a list of the conditions under which a stationary, general-purpose radiographic system is required to provide PBL. This list would replace the present § 1020.31(e)(2)(iv), which describes those circumstances when PBL may be bypassed. The system would be required to provide PBL when all the conditions proposed in § 1020.31(e)(3) are met. The conditions are described below.

(a) PBL would be required if the image receptor is placed in a permanently mounted cassette holder. This provision is not a change from the current standard, which states that PBL may be bypassed when the cassette holder is not used. In this context, cassette trays mounted under stationary X-ray tables are considered to be permanently mounted cassette holders.

(b) PBL would be required when the image receptor length and width are each less than 20 inches. Imposition of this condition would relax the current requirement of the standard, which requires that PBL be provided for any image receptor size that may be used with the system. This condition would eliminate the requirement for PBL for image receptors having any dimensions greater than 20 inches, such as the 14- by 36-inch film size used for radiography of the full spine.

Currently, only a few beam limitation systems offer PBL capabilities for image receptors with dimensions as large as 36 inches. These systems are operable only at a few image receptor sizes, including 14 to 36 inches. Because of the small size of the potential market for PBL systems with the capability to accept these larger cassette sizes as well as a variety of other image receptor sizes, manufacturers have been reluctant to develop more versatile PBL systems capable of accepting a variety of image receptor sizes, including the larger sizes needed by some practitioners. The proposed amendment would permit these practitioners to use cassette holders that provide PBL at image receptor sizes smaller than 20 inches, and PBL would not be required for larger image receptors.

The Commissioner concludes that the benefit to be derived from this change outweighs any potential for increased exposure as a result of not requiring PBL for the large image receptor sizes. The 1970 X-ray Exposure Study conducted by the U.S. Public Health Service indicated that only approximately 0.2 percent of all radiographic examinations in 1970 were examinations of the full spine, the principal use of 14- by 36-inch film.

(c) PBL would be required if the X-ray beam axis is oriented either horizontally or vertically and the SID is within the specified range during the entire exposure. A range of SID's for which PBL is required to be provided would be specified in proposed § 1020.31(e)(3)(iii). Specification of such a range is necessary to clarify the requirements of the standard and to minimize the complexity and cost of the PBL feature.

The current standard requires that PBL be provided at any SID at which the system is capable of functioning. Owing to technical problems associated with providing PBL for larger film sizes, such as 14 by 17 inches, at SID's less than 36 inches, the agency issued interpretations that stated that PBL would not be required for SID's less than 36 inches. The Commissioner proposes to incorporate this interpretation into the regulations by establishing a lower limit of 36 inches for the SID's at which PBL is required. The Commissioner notes that unpublished data from the Nationwide Evaluation of X-ray Trends survey show that less than 3.5 percent of all medical radiographic examinations are performed at SID's less than 36 inches. Thus, the reduction in unnecessary radiation exposure that might be realized from requiring PBL for SID's less than 36 inches would be small and is not judged to be warranted in view of the added expense such a requirement would entail.

Because the SID-sensing mechanism must have a physical upper limit, the Commissioner considers it reasonable to establish an upper limit for the PBL region. For a vertical beam direction, it is proposed that PBL not be required for SID's greater than 50 inches. This limitation would include the most commonly used SID's for which PBL is required. For a horizontal beam direction, an upper limit of 80 inches is proposed for the SID's for which PBL would be required.

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PBL is currently required when the beam axis or table angulation is within 10 degrees of the horizontal or vertical during the entire exposure. During the development of the diagnostic X-ray standard, it was expected that PBL could be provided for angulations of up to 10 degrees from the horizontal or vertical without difficulty. The choice of 10 degrees as the demarcation between the region where PBL is required and the region where bypass is allowed is somewhat arbitrary. The intent was to have PBL for those orientations when the beam axis was perpendicular or nearly perpendicular to the plane of the image receptor and to avoid the technical complexities and costs necessary to provide PBL throughout the full range of beam axis and image receptor orientations. This decision also recognized that the majority of examinations are made with the beam axis either horizontal or vertical.

Problems have been described that result from the requirement for PBL at angles less than 10 degrees when the X-ray table is rotated about an axis that is not coincident with the center of the cassette tray or bucky. Under certain conditions the PBL requirement results in the inability to obtain exposure of the entire area of the X-ray film; in other cases it may result in X-ray fields that are larger than the image receptor. Consideration of this problem and current table designs demonstrates that PBL can be provided if the angular range is reduced to plus or minus 3 degrees. This smaller angular range will ensure that PBL is provided when the X-ray beam axis is approximately perpendicular to the image receptor, yet it will allow those special procedures that have proved troublesome in the past. Therefore, the Commissioner proposes that PBL be required only if the X-ray beam axis is within 3 degrees of the horizontal or vertical and is perpendicular to the plane of the image receptor to within plus or minus 3 degrees.

(d) PBL would not be required during stereoscopic radiography if the X-ray system is designed to provide this capability. This condition is not a change from the current standard, which provides that PBL may be bypassed during stereoscopic radiography.

The conditions for PBL that would be contained in proposed § 1020.31(e)(3) would define when the beam-limiting device must provide PBL. The statement of the requirement for PBL in this manner eliminates the need for reference to bypass of PBL or to automatic return to the PBL mode upon change of image receptor or return from a non-PBL mode of operation. Whenever the conditions contained in proposed § 1020.31(e)(3) are satisfied, the system would be required to provide PBL.

3. *Measuring compliance.* The method of determining compliance with the requirements for PBL would be contained in proposed § 1020.31(e)(4). These methods are the same as in the current standard. Compliance with the requirements of proposed § 1020.31(e)(2) would be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance with the requirement that the X-ray field be limited to the size of the image receptor or production of X-rays be prevented would not be tested during the first 5 seconds after insertion of the image receptor to permit automatic systems to complete the adjustment. This requirement is currently contained in § 1020.31(e)(2)(i).

4. *Override of positive beam limitation.* The capability to override the means for limitation of the X-ray field specified in proposed § 1020.31(e)(2) would be described in proposed § 1020.31(e)(5). In addition to the current provision of the standard that permits override of PBL by means of a captured key switch, the proposed amendment would permit the provision of override switches that do not require a key, provided these switches are not accessible to the user and are not referenced as operator controls in the information provided to users. This amendment would recognize the need for such controls for use by servicemen or repairmen. Although not specifically addressed in the current standard, such a service or repair override capability has been provided on some systems. To discourage inappropriate use by unqualified personnel it is necessary that such controls not requiring a captured key be separated from the normal operator controls.

It is also proposed to require labeling of the override key switches accessible to the operator to indicate the proper function of these switches and to discourage their inappropriate use. The potential for radiation exposure reduction provided by PBL is not realized if these systems are improperly used. The proper purpose of the override capability that is accessible to the operator should be to permit continued use of the X-ray system as a manual system without PBL in the event of a failure of the PBL system. Information received by the agency from its personnel conducting inspections of X-ray systems in user facilities and from State and local radiation control authorities indicates that the override capability is sometimes improperly used, resulting in the loss of the exposure reduction potential provided by the PBL system.

The improper use of the override capability seems to result from two principal reasons. Users of the PBL system are unfamiliar with the functioning of the system and use the override when its use is not necessary, or users lack confidence in the reliability of the PBL system and use the override in an attempt to reduce or prevent malfunctioning of the X-ray system. The Commissioner proposes to reduce the inappropriate use of the override capability due to the first reason by requiring that the override switch be clearly labeled to indicate its intended purpose. Although the agency is concerned about the use of the override as a result of poor system reliability, the competition between manufacturers producing these systems should result in improved reliability as purchasers become more sophisticated concerning the performance of various systems.

It is proposed to require in § 1020.31(e)(5) that the override key switch accessible to the user be labeled as follows: "FOR X-RAY FIELD LIMITATION SYSTEM FAILURE." The current standard in § 1020.31(e)(2)(v) describes an override capability that may be provided in the event of system failure or to perform special procedures that cannot be performed in the positive mode. Reference to use of the override capability to perform special procedures is being omitted in the revision of the requirements for PBL. The Commissioner is aware of no special procedure in which the conditions for PBL as contained in proposed § 1020.31(e)(3) would be met and which would also necessitate that the PBL feature be overridden.

The revisions of the requirement for positive beam limitation, except for the requirement that the keyed override switch be labeled, will not mandate design changes for beam-limiting devices that meet the current requirements for PBL. Systems that comply with the current standard will, except for the labeling requirement, comply with the proposed amendments. The amendments will, however, permit additional flexibility in future designs of these systems to provide performance features desired by users. Because the only additional requirement imposed by these amendments is the requirement that the override switch be labeled to indicate its function, it is proposed that the amendments to § 1020.31(e) become effective 60 days after their publication as a final rule.

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Override of Automatic Beam Limitation for Fluoroscopic and Spot-Film Systems

The Commissioner proposes to recognize in the performance standard the provision of a capability to override the automatic beam limitation devices of fluoroscopic and spot-film X-ray systems. Although override of automatic beam limitation devices has been addressed in the standard for radiographic systems, no such provisions have applied to fluoroscopic or spot-film systems. Because these systems are also susceptible to malfunction, it is proposed that in case of failure of the automatic beam limitation system, override of these devices be permitted to allow their operation in the manual mode, with adjustment of the X-ray field accomplished by the user.

It is proposed that the switch for such an override feature be clearly labeled; however, a captured key switch is not proposed. If the automatic beam limitation system fails during a critical procedure, the fluoroscopist should not have to search for a key. The fluoroscopist should be aware, however, that the automatic beam limitation system has been disabled. Therefore, it is proposed that a signal, visible at the fluoroscopist's position, be provided to indicate when the automatic beam limitation feature is overridden. The override feature would only apply to the X-ray field size adjustment. The other requirements concerning centering the X-ray field on the image receptor, providing capability to adjust the X-ray field smaller than the image receptor, and containing the X-ray field by the primary protective barrier would remain applicable when the automatic beam limitation feature is overridden. This override capability would be addressed in new §§ 1020.31(g)(5) and 1020.32(b)(3).

Because the provision of visual indication at the operator's position could necessitate redesign for systems that do not have such a feature, it is proposed to make the requirement for visual indication when an override switch is provided on spot-film or fluoroscopic beam limitations systems effective 1 year after the date of publication of the final rule based on this proposal.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment and other pertinent background data on which the Commissioner relies in promulgating these amendments are on file with the Hearing Clerk, Food and Drug Administration, and may be seen between 9 a.m. and 4 p.m. Monday through Friday.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 1020 be amended as follows:

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Part 1020

§ 1020.30
§ 1020.31
§ 1020.32

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[FR Doc. 78-12386 Filed 5-8-78; 8:45 am]

30.—Radiation Therapy Simulation Systems

†30.3 Proposal—August 3, 1979

– 44 FR 45645 –

[21 CFR Part 1020]

[Docket No. 79N-0148]

Diagnostic X-ray Systems and Their Major Components; Amendments to Performance Standard

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend the performance standard for diagnostic x-ray systems and their major components to (1) revise the definition of a "radiation therapy simulation system"; (2) raise the maximum allowed aluminum equivalent thickness for radiation therapy simulator table tops; (3) exempt radiation therapy simulator light localizers from requirements concerning minimum illumination; and (4) exempt fluoroscopic therapy simulator systems from requirements concerning maximum allowable entrance exposure rates. The amendments would bring applicable provisions of the standard into agreement with existing manufacturing, marketing, and clinical practices as well as with existing FDA interpretations and variances.

DATE: Comments by October 2, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Robert Phillips, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: Since the diagnostic x-ray equipment performance standard (§§ 1020.30, 1020.31, and 1020.32 (21 CFR 1020.30, 1020.31, and 1020.32)) was proposed (36 FR 19607, October 8, 1971), several questions have been raised by manufacturers and other interested parties concerning the applicability of specific requirements of the performance standard to radiation therapy simulators. In particular, petitions for variance were submitted by four radiation therapy simulator manufacturers before the effective date of the standard (August 1, 1974). All four products were fluoroscopic x-ray systems designed exclusively for therapy simulation, and all four petitions dealt with essentially the same aspects of fluoroscopic x-ray system performance. FDA determined at that time that the arguments given by manufacturers in their petitions were valid, i.e., compliance with the standard would impair the accuracy and effectiveness of the simulation while the additional dose to the patient resulting from the relaxed requirements for radiation therapy simulators would not be significant when compared to the dose received from the radiation therapy treatment itself.

Therefore, a notice of proposed rulemaking was published in the Federal Register of July 22, 1974 (39 FR 26651) and the proposed amendments were published as a final rule (39 FR 36008) on October 7, 1974. The amendments stated that radiation therapy simulators were:

(1) Fluoroscopic x-ray systems intended for localizing the volume of

tissue to be irradiated during radiation therapy (§ 1020.30(b)(50));

(2) Exempt from the requirements of § 1020.31(g) (21 CFR 1020.31(g)) for spot-film devices;

(3) Exempt from the requirement for a primary protective barrier (§ 1020.32(a)(1) (21 CFR 1020.32(a)(1))) if operated remotely and if appropriate information was provided to users;

(4) Exempt from the field alignment requirement for image-intensified fluoroscopy (§ 1020.32(b)(2)); and

(5) Allowed to have a cumulative on-time timing device that did not produce an audible signal after 5 minutes of x-ray production (§ 1020.32(g)).

Although these amendments recognized the need for specific provisions in the performance standard for the radiation therapy simulator, the agency has since become aware of other problems relating to this type of equipment that should be addressed by further amendments to the standard. FDA, therefore, proposes the following specific amendments:

(1) The definition for a radiation therapy simulator system in § 1020.30(b)(50) would be revised by changing the phrase "fluoroscopic x-ray system intended for" to read "radiographic or fluoroscopic x-ray system primarily intended for."

The current definition of a radiation therapy simulator in § 1020.30(b)(50) recognizes only fluoroscopic-type simulator systems. Some radiation therapy simulator systems now being marketed, however, are radiographic rather than fluoroscopic. Because radiographic therapy simulator systems do not fit the current definition and because the radiographic type therapy simulators are designed for the visualization of any part of the body, under current regulations they would be classified as general purpose radiographic x-ray systems. The systems would then be subject to the positive beam limitation (PBL) requirements of § 1020.31(e)(2). The October 1974 amendment to the standard recognized that fluoroscopic therapy simulators should be relieved from the beam limitation requirements of §§ 1020.31(g) and 1020.32(b)(2) because the requirement interfered with the accurate use of the device and relief from these requirements would not significantly increase the radiation exposure to the patient. The agency believes that the same arguments apply to radiographic therapy simulator systems and the PBL requirements of the performance standard. Furthermore, all known radiographic x-ray systems designed for therapy simulation have radiopaque markers permanently mounted in the useful x-ray beam. These markers are used to outline the therapy treatment field on a simulator film and preclude the use of these systems as general purpose systems. In recognition of these conditions, an advisory opinion was sent to manufacturers on July 22, 1976, stating that radiographic radiation therapy simulator systems would be considered "other than" general purpose radiographic x-ray systems and thus subject to the field limitation and alignment requirements of § 1020.31(f)(4) rather than § 1020.31(e)(2). This proposal would formalize that advisory opinion by changing the definition of radiation therapy simulators to include radiographic systems.

(2) Section 1020.30(n) currently limits radiation therapy simulation system table tops to 1.5 millimeters (mm) maximum aluminum equivalent thickness of material between the patient and image receptor. The agency proposes to raise this value to 5.0 mm.

Recently, a variance was granted to EMI Therapy Systems, Inc. (43 FR 9862, March 10, 1978) allowing the manufacture of therapy simulator tables whose thickness exceeded the limits allowed by § 1020.30(n). The variance was granted because it was demonstrated that the positional stability necessary for accurate simulation could not be obtained with a cantilevered table whose thickness was less than 1.5 mm aluminum equivalent. In addition, it was shown that the net increase in dose to the patient from the significantly thicker table proposed by the manufacturer would be much less than one percent of any anticipated treatment dose. FDA has determined that the arguments made in the variance petition would be applicable to all radiation therapy simulator tables. The agency, therefore, proposes to raise the maximum equivalence limit of § 1020.30(n) for radiation therapy simulator table tops to 5.0 mm.

(3) The proposed amendment to § 1020.30(d)(2)(ii) would exempt radiation therapy simulator systems from the requirements specifying minimum illumination for defining x-ray fields.

Several manufacturers have indicated difficulty in meeting the minimum illumination requirement of § 1020.31(d)(2)(ii) and still manufacture equipment capable of accurately defining the simulated treatment field. The minimum illumination requirement leads to the use of light bulbs with fairly large filaments for adequate heat dissipation. However, radiation therapy simulators provide various scales and visual guides projected in the light field which are used in the simulation. Because of penumbra effects, the accuracy of the scales and guides is lost when a large filament bulb is used. Therefore, the minimum illumination requirement can lead to less accurate and effective treatment planning. The agency believes that because the light field is an essential feature in the simulation, it must necessarily be bright enough to be visible under ambient lighting conditions. It is unlikely that a therapy simulator would be manufactured with a light field that will not adequately define the x-ray field. The minimum illumination requirement is therefore unnecessary and detrimental to proper radiation treatment planning.

(4) Fluoroscopic radiation therapy simulators would be exempt from the maximum exposure rate limits specified in § 1020.32(d).

Some types of fluoroscopic radiation therapy simulators are designed to simulate a very wide range of treatment types. Such systems must necessarily provide a large range of source-to-skin distances (SSD's). If the system is adjusted to meet the exposure rate limits of § 1020.32(d)(1) at the smallest SSD, an inadequate image could be produced at the largest SSD. One possible solution would be to tie the x-ray source output into an x-ray source position sensor, but this would add unnecessary complexity and expense to the system. Other types of solutions are possible, but they also add considerable expense and/or do not allow the most effective means of simulation. FDA believes that, because these devices are used only on patients who are scheduled to receive radiation therapy doses of hundreds to thousands of rads, the slight increase in patient dose that will result from relaxing the entrance exposure limit for fluoroscopic therapy simulator systems is not significant. Therefore, the agency proposes to exempt fluoroscopic radiation therapy simulators from the requirement of § 1020.32(d).

FDA proposes that these amendments become effective on the date of publication of the final rule in the FEDERAL REGISTER. This early effective date is considered feasible because the new provisions contained in the regulation are for clarification and are consistent with interpretations that have been issued previously.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 1020 be amended as follows:

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Part 1020

§ 1020.30

§ 1020.31

§ 1020.32

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[FR Doc. 79-23641 Filed 8-2-79; 8:45 am]

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G. Microwave Ovens

2.—Amendment of Performance Standards

†2.4 Notice of Availability of Petition Guideline—December 22, 1978

- 43 FR 59906 -

[Docket No. 78D-0405]

EXEMPTION FROM CERTAIN MICROWAVE OVEN LABELING

Availability of Petition Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces the availability of "Guidelines for Exemption From the Microwave Oven Labeling Requirements of 21 CFR 1030.10(c)(6)(i)," which has been developed to aid microwave oven manufacturers in preparing petitions for exemption from labeling requirements of the radiation safety performance standards. The guideline also contains a summary of the basis for the tests and criteria, and the rationale for each of the substantive provisions. This notice also reviews the procedures used for the development of the guidelines. Although issued in final form, these guidelines may be subject to revision on the basis of scientific and technical information not previously considered, and the agency invites interested persons to submit pertinent information, data, and comments. Revisions will be developed in a manner similar to that used for preparation of the original guidelines.

DATE: After June 20, 1979, exemptions are to be based on criteria contained in the guidelines or their equivalent. Comments submitted by March 22, 1979, will be considered in the preparation of appropriate revisions.

ADDRESS: Comments should be submitted to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Copies of the guideline are available from the Bureau of Radiological Health (HFX-430), 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Albert Van De Griek, Bureau of Radiological Health (HFX-430), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6540.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 2, 1975 (40 FR 14750), the Commissioner of Food and Drugs amended the performance standard for microwave ovens (§ 1030.10 (21 CFR 1030.10)). Section 1030.10(c)(6)(i) of the standard requires that a warning label, intended primarily for oven users, be attached to the ovens. Section 1030.10(c)(6)(iv) provides for an exemption from one or more of the label warning statements upon application to, and approval by, the Director, Bureau of Radiological Health. In the preamble to the April 1975 amendment, the Commissioner stated that the exemption would be granted if an evaluation of the application, based on certain criteria, were to show a very low probability of occurrence of the radiation exposure situation for which the exemption is sought. The Director of the Bureau of Radiological Health has received several applications from manufacturers for exemption from the labeling requirements. Consideration of these applications indicates that guidelines would be helpful to manufacturers and the Bureau to aid in the preparation and evaluation of such applications.

The Commissioner believes that more definitive guidance on tests and criteria to be used in applying for, and evaluating, exemption requests is needed. Accordingly, on March 31, 1978, the Bureau of Radiological Health distributed a draft of the criteria and related information to microwave oven manufacturers, the Association of Home Appliance Manufacturers (AHAM), and Consumers Union and invited their review and comments. Six manufacturers, AHAM, and Consumers Union responded to the invitation to comment. The Bureau has carefully considered these comments and prepared a summary and analysis of them. The draft criteria, comments, analysis of comments, and related documents have been filed with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. On the basis of the analysis of comments, and other relevant information, the criteria and testing guidelines have been compiled in a document entitled "Guidelines for Exemption From the Microwave Oven Labeling Requirements of 21 CFR 1030.10(c)(6)(i)," which is available upon request from the Bureau of Radiological Health (HFX-430), 5600 Fishers Lane, Rockville, MD 20857. This document also contains a summary of the rationale for the criteria and testing information.

Although the guideline has been issued in final form, it may be revised on the basis of scientific and technical information not previously considered. The Commissioner advises that an exemption will not be granted and any previously granted exemption will be rescinded after June 20, 1979, unless the manufacturer has demonstrated to the satisfaction of the Director of the Bureau of Radiological Health that the microwave ovens for which the exemption is requested, or was previously granted, conform to these guidelines or their equivalent. Comments, suggested changes, and supporting information may be submitted to the Hearing Clerk (address above), at any time (preferably in four copies identified with the Hearing Clerk docket number). Comments received by March 22, 1979, will be considered in the preparation of revised guidelines. Received comments will be incorporated into the public file on the guideline and may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday, except holidays.

* * * * *

[FR Doc. 78-35425 Filed 12-21-78; 8:45 am]

V. Light-Emitting Products

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D. Laser Products

2.—Amendment of Performance Standards

†2.2 Final Regulation—November 28, 1978

– 43 FR 55387 –

[Docket No. 77N-0074]

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

Laser Products

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: This rule amends the laser products performance standard to remove unneeded criteria for determining human access to laser or collateral radiation; specify more appropriate parameters for measuring the accessible emission levels of laser and collateral radiation, including scanned laser radiation; relax the accessible emission limits for collateral radiation in the wavelength range of greater than 400 nanometers (nm); relax the labeling and performance requirements for some Class II laser products; and allow more administrative flexibility in determining the wording of warning labels.

DATES: Effective December 8, 1978, except for § 1040.10(h)(2) (i) and (ii) which will be effective January 29, 1979, for laser products that are manufactured on or after these dates; comments by January 29, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn E. Conklin, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs issued a notice of intent, published in the FEDERAL REGISTER of April 1, 1977 (42 FR 17495), to amend the performance standard for laser products (§ 1040.10 (21 CFR 1040.10)). That notice described the amendments being considered as a result of experience gained in administering the performance standard. Interested persons were invited to submit written data, views, or arguments concerning those amendments and any associated potential environmental and economic impact. A draft of the amendments was distributed widely to manufacturers, professional associations, consumer groups, government agencies, and individuals who had requested information about laser products from the Bureau of Radiological Health of the Food and Drug Administration (FDA). Subsequently, the draft amendments and the basic concepts for them were discussed publicly at the May 5, 1977 meeting of the Technical Electronic Product Radiation Safety Standards Committee. Under the Radiation Control for Health and Safety Act of 1968, this statutory committee must be consulted prior to the establishment of any electronic product performance standard. The Committee and others generally supported the concepts involved in the amendments and suggested revisions to eliminate possible ambiguities.

The Commissioner therefore finds that further notice and public procedure on these amendments are unnecessary, and that more than adequate notice and opportunity for comment have already been provided.

EFFECTIVE DATE

These amendments would reduce the burden on affected manufacturers and the cost to the consumers without compromising the public health and safety. Also, no manufacturer with a currently compliant product would need to redesign his or her products in order to comply with the proposed amendments, and there would be greater design latitude within each of the graded risk classes for laser products. Therefore, it has been determined that pre-effectiveness delay concerning these amendments is unnecessary and would be contrary to the public interest by delaying realization of the cost savings that are anticipated to result from their implementation.

The Commissioner concludes, therefore, that good cause exists and that the public interest would best be served by making this amendment to the performance standard effective December 8, 1978, except for § 1040.10(h)(2) (i) and (ii) which will be effective January 29, 1979; the purchasing and servicing information specified in § 1040.10(h)(2) pertaining to Class IIa laser products will need to be printed.

At the same time, the Commissioner invites and encourages public comment on this action. Interested persons may on or before January 29, 1979, file with the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, four copies of written comments on this amendment, identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday. Any changes in this regulation justified by the comments will be the subject of a further amendment.

HUMAN ACCESS

As indicated in the April 1, 1977 notice, the Commissioner has reviewed the criteria of § 1040.10 for determining human access to laser and collateral radiation and has concluded that some of these criteria can be eliminated without affecting the protection afforded the public by the standard.

The current definition of "human access" in § 1040.10(b)(12) involves the concepts of access to laser or collateral radiation at a point by any part of the human body, by a straight line having an unobstructed length of 100 centimeters (cm), or by any line having an unobstructed length of 10 cm. The reference to a 10-cm line was included in the original definition to account for the possible insertion of flexible optical fibers, mirrors, or similar materials into a laser product. However, the Commissioner has concluded that the additional degree of safety provided by this requirement does not justify the added design difficulty that it poses. The Commissioner also finds the definition of "human access" overly restrictive when the criterion involving a 100-cm straight line is applied to collateral radiation. Collateral radiation arises from other than point sources and is difficult to collect and to focus into a diffraction-limited spot. Therefore, the Commissioner has revised the definition for "human access" to clarify the definition and to delete (1) any reference to a 10-cm line and (2) reference to a 100-cm line for collateral radiation. The revised definition now clearly states that human access means access at a particular point to laser or collateral radiation by any part of the human body or access to laser radiation (but not collateral radiation) by a straight unobstructed path of up to 100 cm from any part of the body, including the eye.

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The Commissioner notes that, after reviewing the draft amendments and in response to the April 1, 1977 notice, several persons, including members of the Technical Electronic Product Radiation Safety Standards Committee, suggested that the definition of "human access" should specify a minimum diameter for the 100-cm straight line.

The Commissioner disagrees with this suggestion and notes that a test object of specified diameter was included in the performance standard for microwave ovens in § 1030.10 (21 CFR 1030.10) and was found unsatisfactory as a concealed safety interlock criterion. Products could be designed to meet the literal requirements of this criterion, although many common household objects could be used to circumvent its intent (see 40 FR 27038 (June 26, 1975) and 40 FR 52007 (Nov. 7, 1975)). The new definition for human access and the acceptance angle and collimating optics (discussed later in this preamble) will enable manufacturers to design a more open protective housing using perforated or grille panels for their products, as long as the design does not permit any unobstructed straight-line path of less than 100 cm through the protective housing to the laser radiation. The Commissioner concludes that specifying a minimum diameter for the line would defeat the benefits of the new definition without any apparent increase in protection of the public health.

Other portions of § 1040.10 have been revised to clarify concepts of human access. The definition of "accessible emission level" in § 1040.10(b)(1) has been changed to express more clearly that the term refers to the magnitude of the radiation at a particular point. Section 1040.10(f)(3) concerning the remote control connector has been clarified by substituting "available" for "accessible." For consistency, "human" has been added to § 1040.10(h)(2)(ii) so that the requirement reads, in part, "displaceable portions of the protective housing that could allow human access to laser or collateral radiation."

The experience of FDA is that the beam attenuator specified in § 1040.10(f)(6) is used only with laser products for which access to laser and collateral radiation during operation is necessary to perform the product's function, and that the criteria of § 1040.10(b)(12) for determining human access to the radiation are not appropriate. Thus, the Commissioner is amending § 1040.10(f)(6) to specify that the beam attenuator, when in use, shall simply prevent access to radiation by any part of the human body. The emission indicator and aperture label would still indicate the possible presence of the laser radiation.

A comment made by some members of the Technical Electronic Product Radiation Safety Standards Committee indicated the term "viewable" in § 1040.10(f)(8) was not clear.

The Commissioner agrees with this comment, and the viewing optic requirement in § 1040.10(f)(8) has been restated to include the specific concept of accessibility of laser and collateral radiation to the human eye only by means of viewing optics, viewports, or display screens, rather than the generalized concept of accessible radiation; access of the human eye to laser or collateral radiation is the key issue.

ACCEPTANCE ANGLE AND COLLIMATING OPTICS FOR MEASUREMENTS

The accessible emission limits for laser products, expressed in terms of irradiance, radiant energy, or radiant power, are based in part on collimated laser and collateral radiation that can be collected in an optical system having a small angle of acceptance and can be made equivalent to a narrower beam of radiation. The Commissioner concludes that the performance standard is overly restrictive with regard to multiple, extended, and divergent sources of radiation, and that different parameters for measuring the accessible emission levels of laser and collateral radiation need to be specified. Therefore, the Commissioner is amending § 1040.10(b)(18), (e)(3), and (e)(4) to include the concepts of the acceptance angle and collimating optics. By this change the standard will be more appropriate for multiple, extended, and divergent sources of radiation that do not present the same hazard as virtual point sources capable of producing highly collimated beams. The Commissioner is not amending that part of § 1040.10(e)(3)(ii) relating to the measurement of radiant exposure because these measurements of accessible laser radiation are needed only to determine if the upper limits of Class III, as specified in Table I-C of § 1040.10(d), are exceeded and these levels of laser radiation are both eye and skin hazards even upon diffuse reflection.

The Commissioner adds that, except for radiance measurements, the acceptance angle for the measurement of the other radiometric quantities is not specified directly in the standard. An acceptance angle of 2 pi steradians, established as part of the tests for determining compliance, is however based upon the criteria in § 1040.10(e)(2) and considers the maximum collectible radiation. This regulatory interpretation was necessary to account for the most hazardous situation, but may be unnecessarily restrictive with regard to multiple, extended, and divergent sources, when the question to be considered is how well collimated the laser and collateral radiation must be to be collected and focused on a small area of the skin, cornea, or retina.

One comment in response to the April 1977 notice suggested the introduction of a variable acceptance angle to match the dual accessible emission limits specified in § 1040.10(d)(4) to determine if laser or collateral radiation exceeds the limits of Class I. The comment recommended that magnitudes of the limiting angular subtense (α(min)) in the American National Standard Z136.1-1976 be used for the acceptance angle.

The Commissioner rejects the comment and maintains that using a variable acceptance angle for the instrumentation would unnecessarily complicate the measurements needed to determine a product's compliance with the standard. Further, the Commissioner intended the integrated radiance alternative of the dual limits included in § 1040.10(d)(4) to accommodate extended sources (real or virtual) such as holographic images, diffuse reflections, transmissions through diffusers, or diffuse collateral radiation, and notes that the dual limits of Class I are exceeded only if the limits for radiant energy and integrated radiance are exceeded; consequently, the dual limits of Class I are less restrictive than if a variable acceptance angle were used.

The standard in § 1040.10(d)(4) establishes limits for Class I from two perspectives. One limit, expressed as integrated radiance, pertains to the accessible emission level measured as a function of the brightness of the source; the other relates to the accessible emission level measured as the radiant energy incident upon the detector. The largest acceptance angle derived from these accessible emission limits for radiant energy measurements is 5×10^{-4} steradian, using a 7-millimeter (mm) diameter aperture stop. A somewhat larger solid angle of acceptance of 1×10^{-3} steradian provides more safety and is equivalent to a circular cone of acceptance of approximately 2 degrees diameter. Therefore the standard is being amended in § 1040.10 (e)(3) and (e)(4), where appropriate, to require a specific acceptance angle of 1×10^{-3} steradian when determining the accessible

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emission levels of laser and collateral radiation.

The Commissioner has determined that § 1040.10(e) is ambiguous as to the minimum size of a source of laser or collateral radiation that must be considered when measuring the radiance or integrated radiance because a source may be small or have a nonuniform spatial distribution. The size of the source to be considered depends upon the distance of the detector from the product. The closest approach of a person's eye to a point source of light at which a sharply focused retinal image is still produced is called the distance of maximum accommodation; moving closer to the point source would cause the spot formed on the retina to enlarge and the image to blur. According to published research, 20 cm is the average distance of maximum accommodation expected for 37-year old humans; older persons are expected to have a greater accommodation distance and younger persons a lesser distance (Ref. 1). A power of 5 diopters (the focusing power of a lens, expressed in diopters, is the reciprocal of the focal length, expressed in meters) for the collimating optics represents a 20-cm minimum focal distance. Utilizing the collimating optics of 5 diopters or less means that the source area of approximately 0.7 mm or larger in diameter that results in the maximum level will be considered in determining the accessible emission level in terms of radiance. Therefore, the standard is being amended to require collimating optics of 5 diopters or less as an additional measurement parameter to be used in conjunction with the aperture stops in the tests for determining compliance.

The Commissioner also recognizes that the combination of collimating optics and aperture stop establishes a collection angle for the aperture stop for divergent radiation emitted by a point source. The collection angle is twice that angle whose tangent is the ratio of the aperture stop radius to the distance of the aperture stop from point of emission of radiation on the product. In most instances this distance will be the focal distance of the collimating optics, modified by the acceptance angle of the aperture stop to maximize the collection of accessible radiation. The maximum collection angle is about 22 degrees for the 80-mm diameter aperture stop and about 2 degrees for the 7-mm diameter aperture stop.

The concepts of the acceptance angle of 1×10^{-3} steradian and the collimating optics of 5 diopters have been developed using information applicable primarily to the visible spectrum; however, the original intent of the agency is retained when these concepts are utilized in the ultraviolet and infrared spectral regions. Simple focusing optics are available that will concentrate well collimated radiation in these spectral regions.

RADIATION INTENDED TO BE VIEWED

Laser products have accessible laser and collateral radiation that may be grouped into two categories: (1) radiation that is intended to be viewed directly and frequently, though not exclusively, by way of display screens, viewports, or microscopes when such viewing is necessary to achieve the intended function of the product; and (2) radiation that is not likely to be viewed for extended periods of time, either because use of the product would not require operators and others to view the radiation to perform the functions of the product or because no characteristics of the radiation would attract a person's gaze for long periods. The Commissioner believes the second category can be incorporated into the standard for appropriate types of laser products.

Accessible laser radiation of Class III is at levels at which biological damage to human tissue is possible from acute direct exposure. Similarly, accessible laser radiation of Class IV is at levels at which biological damage is possible from acute direct or diffuse exposure. Thus, the requirements relating to Class III and IV cannot be relaxed on the above basis. By contrast, Class II accessible laser radiation is at levels of visible radiation at which eye damage from chronic exposure is possible. However, Class II laser radiation is bright and can be uncomfortable to view, especially the higher levels of Class II. The Commissioner believes a person would not view such a light source for more than 1 × 10^3 seconds (16.7 minutes), unless there were some compelling reason. Chance viewing of Class II levels or laser radiation that do not exceed the accessible emission limits of Class I for any emission duration less than or equal to 1 × 10^3 seconds is not expected to be hazardous.

Therefore, the Commissioner is amending the standard to add a new subclass for laser products, Class IIa, and to amend § 1040.10(f)(5), (f)(6), (g)(1), and (g)(4) to provide for special considerations within Class IIa. Class IIa products are exempted from the requirements for a laser radiation emission indicator, beam attenuator, Class II warning logotype, and aperture label. As amended, the standard requires Class IIa laser products to bear a class designation label with instructions to avoid long-term viewing of the direct laser radiation. The class designation label, because it does carry a warning statement to the operator of the Class IIa product, must be visible during operation as required by § 1040.10(g)(10) and must be reproduced in purchasing and servicing information as required by § 1040.10(h)(2)(i).

Also, the Commissioner is extending this concept to collateral radiation by amending the standard to increase the long-term level of collateral radiation permitted by reducing the applicable maximum emission duration used in determining the accessible emission level (Table III of § 1040.10(d)). This change for radiation in the wavelength range of greater than 400 nm but less than 13,000 nm decreases the maximum emission duration from 1 × 10^4 seconds to 1 × 10^3 seconds, but does not apply either to radiation that is accessible to the human eye by means of viewing optics, viewports, or display screens (§ 1040.10(f)(8)), or to ultraviolet collateral radiation because a cumulative damage mechanism is likely.

EMISSION INDICATORS AND COLLATERAL RADIATION

Some members of the Technical Electronic Products Radiation Safety Standards Committee have commented extensively in their last two meetings concerning the provisions of the laser standard and the agency's policy with respect to the light emitted from the pilot light on laser products.

The standard requires in § 1040.10(f)(5) that each laser product of Class II or greater incorporate an emission indicator. Nowhere does the standard require that the emission indicator be a pilot light, although manufacturers have found a pilot light a convenient means for satisfying the requirements of § 1040.10(f)(5). The Commissioner believes that the radiation from laser product pilot lights should not be considered collateral radiation because, to be collateral radiation, such radiation must be emitted by a laser product as a result of the operation of the laser(s) or be emitted by any component that is physically necessary for the operation of the laser(s) incorporated into that product. Collateral radiation includes, for example, light from the laser-tube plasma glow, light from the flashlamp for exciting the laser medium, and x-radiation from the laser energy source (components that are physically necessary for the operation of the laser). Collateral radiation does not include emissions from a pilot light because it is not physically necessary to the operation of the laser. The Commissioner concludes that the definition for collateral radiation needs clarification and amends § 1040.10(b)(9) accordingly.

MEASUREMENT PARAMETER FOR SCANNED LASER RADIATION

A comment received before the effective date of the standard, August 2,

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1976, suggested that in some cases, high levels of accessible scanned laser radiation could be reduced below the Class I limits by varying the apparent origin from which the scanned pattern is emitted. This type of radiation source can be regarded as an apparent extended source.

The Commissioner believes the standard should provide for the apparent extended sources of laser radiation. The standard currently provides in § 1040.10(e)(4) that the accessible emission levels of scanned laser radiation shall be determined by the measurement of radiation detectable within a stationary circular aperture stop having a 7-mm diameter. The resulting temporal variation of detected radiation is considered as a pulse or series of pulses. Under § 1040.10(e)(3)(iii), measuring integrated radiance involves a solid angle of acceptance of 1×10^{-5} steradian. However, under § 1040.10(e)(2)(iv) the acceptance angle of the instrument for measuring integrated radiance must be instantaneously so positioned and so oriented with respect to the laser product "as to result in the maximum detection of radiation by the instrument." Conceptually the orientation of the instrument must track the source, but its aperture stop remains stationary. As noted in § 1040.10(e)(3), techniques, including computations, that provide results equivalent to the above are permitted.

Apparent extended sources formed by a moving, well collimated, laser beam can be more hazardous than conventional extended sources. The eye can follow and fix upon a slowly moving source of visible light, but the source can also move so rapidly (e.g., a television image formed by a rapidly scanning electron beam) that the eye cannot follow. The human eye has difficulty tracking an angular motion of 2 radians/second or greater (Refs. 2 and 3.) An effective extended source is achieved when the angular motion of the source transversely to the line of sight of the eye is 5 radians/second or greater. Therefore, the Commissioner is amending § 1040.10(e)(4) to provide that the solid angles of acceptance utilized in the measurement of radiant energy and radiance need not track the source at an angular speed greater than 5 radians/second to maximize the measurement of radiation.

CHANGE IN WAVELENGTH RANGE FOR VISIBLE RADIATION

The introduction of Class IIa into the standard results in anomalies in the classification of certain products that emit accessible laser radiation between 700 nm and 711 nm and at radiant exposure values below the accessible emission limits of Class IIa at 700 nm. For example, a 1-microwatt laser product would be classified in Class IIa if emission were at 699 nm, Class III if emission were at 701 nm, and Class I at 711 nm. However, the original rationale for Class II remains valid because the relative spectral luminous efficiency value, a measure of relative photochemical response of the eye at 710 nm, is still half the value at 700 nanometers (Ref. 4).

Thus, the Commissioner is changing the Class II and Class IIa wavelength boundary to 710 nm where the Class IIa accessible emission limit curve intercepts that for Class I, and all portions of the standard that contain the wavelength 700 nanometers have been revised accordingly.

FLEXIBILITY IN LABELING

Wording of the warning statements specified in § 1040.10(g) has been found on occasion to be inappropriate. Problems in which the size, configuration, or design of the laser product precludes compliance with the label requirements have been readily resolved using the mechanism established in § 1040.10(g)(10); without this mechanism, the lengthy variance procedure of § 1010.4 would have to be used. The Commissioner concludes that similar provisions are appropriate for wording and is amending § 1040.10(g)(10) to permit the Director, Bureau of Radiological Health, on his own initiative or upon written application by the manufacturer, to approve the use of alternate wording on warning labels when the wording prescribed by the standard is inappropriate or would be ineffective because of the size, configuration, design, or function of the laser product.

The warning required by § 1040.10(g)(8) for invisible radiation is amended to permit use of the words "visible and/or invisible" whenever the product may emit any combination of visible and invisible radiation.

REFERENCES

1. Davson, Hugh, "The Physiology of the Eye," 3d ed., Academic Press, New York, pp. 402-403, 1972.

2. Barmack, M., "Dynamic Visual Acuity as an Index of Eye Movement Control," *Vision Research*, 10:1377-1391, 1970.

3. Brown, B., "Dynamic Visual Acuity, Eye Movements, and Peripheral Acuity for Moving Targets," *Vision Research*, 12:305-321, 1972.

4. RCA Electro-Optics Handbook, 1974.

Pertinent background data and information supporting the Commissioner's action are available for public review in the office of the Hearing Clerk (HFA-305), Food and Drug Administration.

On the basis of an amendment to the environmental impact analysis report for the performance standard for laser products, the Commissioner concludes that promulgation of this amendment to the standard will not significantly affect the quality of the human environment and, therefore, that no environmental impact statement is necessary under § 25.1(b) (21 CFR 25.1(b)). A copy of the FDA environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner (21 CFR 5.1), Part 1040 is amended as follows:

* * * * *

Part 1040

§ 1040.10
§ 1040.11

* * * * *

[FR Doc. 78-33137; Filed 11-27-78; 8:45 am]

†E. Mercury Vapor Lamps

†1.—Performance Standards

†1.1 Proposal—April 21, 1978

– 43 FR 16997 –

[21 CFR Part 1040]

[Docket No. 76N-0383]

MERCURY VAPOR LAMPS

Proposed Performance Standard

AGENCY: Food and Drug Administration.

ACTION: Proposed Regulation.

SUMMARY: This is a proposal to establish a performance standard for high-intensity mercury vapor discharge lamps to reduce the possibility of injury from exposure to short wavelength ultraviolet (UV) radiation from broken mercury vapor lamps. The proposed standard would apply to any lamps, including "metal halide" and "self-ballasted" types, that incorporate a high-pressure arc discharge tube with a fill consisting primarily of mercury and surrounded by an outer envelope, that are designed, intended, or promoted for illumination purposes and are manufactured or assembled on or after 6 months after the date of publication of the final regulation based on this proposal.

DATE: Comments by June 20, 1978.

ADDRESS: Written comments (preferably four copies) to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

George C. Jan, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD

20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: Mercury vapor lamps have become a popular light source for illumination because they are efficient in producing light and because their long life and compact size permit easy maintenance and convenient light control. The lamp industry has estimated that more than 25,000,000 mercury vapor lamps are installed in this country. This type of lamp is used in various lighting applications including school gymnasiums, stores, industrial facilities, streets, and highways. Yet members of the public, in general, are not aware of, or do not know how to prevent, the potential radiation hazard associated with the use of these lamps. Such potential radiation hazard occurs when the outer bulb of a mercury vapor lamp is broken while the inner arc tube of the lamp continues to operate. This results in the emission of hazardous short wavelength UV radiation. The short wavelength UV radiation can produce painful short-term effects such as eye irritation and skin burn. Bioeffects studies, including epidemiological studies of human populations, also indicate possible long-term effects of UV radiation, such as premature skin-aging and malignant skin tumors as a result of prolonged or repeated exposure. The injury reports received by FDA in the past 2 1/2 years further indicate an acute radiation hazard from broken mercury vapor lamps. For the protection of the public health it is apparent that the short wavelength UV radiation from a broken lamp should be effectively controlled or eliminated.

In attempting to solve this problem, FDA has collected information through investigations of injury reports, laboratory tests, and communications with lamp manufacturers and has issued hazard warnings and recommendations for safe use. Such information has been distributed to architects, purchasers, users, trade associations, publishers, all State radiation control agencies and the FDA regional and district offices. The agency also has collaborated with representatives of a committee under the American National Standards Institute (ANSI) in the development of a national consensus standard that was approved by the ANSI Board of Standard Review in November 1976.

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The agency has also taken steps under the authority of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, secs. 356, 358 (42 U.S.C. 263d, 263f)) to develop a proposed Federal regulation. A notice of intent to consider the need for a regulatory performance standard and proposed radiation safety criteria for the manufacture of mercury vapor lamps was published in the FEDERAL REGISTER of October 8, 1976 (41 FR 44421). That issuance invited any interested party to comment on the agency's proposed criteria, or other appropriate requirements of a standard, and the possible environmental and economic impacts in establishing such a standard. In addition, the mercury vapor lamp problem and the agency's proposed actions were reviewed on two separate occasions by the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) at their 13th meeting in September 1975 and 14th meeting in April 1976. An FDA status report concerning mercury vapor lamps was presented at the TEPRSSC's 15th meeting on May 6, 1977. The notice of intent and the proposed criteria, the comments received, and the transcripts of advisory committee meetings are on file with the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

The Commissioner is now proposing a regulation that would permit two types of mercury vapor lamps: One that is self-extinguishing and the other that is not. The proposal would require a self-extinguishing mercury vapor lamp to cease operation within 15 minutes or less after the outer envelope is broken so that excessive exposure to such radiation is less likely to occur. Other requirements on lamp and package labeling for both self-extinguishing and non-self-extinguishing lamps are set forth in the proposal, while yet additional requirements for advertising for lamps that are not self-extinguishing are included to assure that adequate information is provided to the user for the safe use of the product. In developing the proposed regulation, FDA has considered all comments received, information from injury reports, the results of testing and research conducted at the agency's laboratories, and radiation protection guidelines developed by other groups such as the occupational UV exposure criteria recommended by the National Institute for Occupational Safety and Health and the voluntary standard for mercury vapor lamps developed by ANSI.

More than 200 comments were received in response to the October 8, 1976 notice of intent. Comments were received from lamp manufacturers, utility companies, and municipal or local governments, as well as the National Rural Electric Cooperative Association. The important issues raised by the comments and the Commissioner's proposed resolution of these issues are summarized as follows:

MERCURY VAPOR LAMP INJURIES

1. In response to a list of topics for which information was specially solicited in the published notice, many comments were received regarding injuries from mercury vapor lamps and steps that should be taken to prevent injuries. Several comments noted that almost all documented injuries and potential dangers were associated with indoor lamp installations of relatively low mounting heights and with prolonged exposures. A number of comments contended that the evidence of human injury or potential hazard was insufficient to warrant any drastic action and questioned the appropriateness of the FDA proposal.

The agency has continued to receive reports of injury resulting from broken mercury vapor lamps. To this date, more than 190 persons in this country reportedly have been injured. This is three times the number of reported injuries on file when the October 1976 notice of intent was published. Although different degrees of hazard may exist for different applications, the Commissioner has concluded that the reported injuries do not demonstrate that all outdoor uses are safe. He also notes that the exposure times as documented in the injury reports only reflected the durations of exposure experienced by the injured persons, but were not the least or minimum exposure times needed to produce injuries. He believes the continued reports of injury clearly demonstrate the need for this proposed standard.

ALTERNATE MEANS OF CONTROL

2. One comment suggested that the obvious means to avoid incidents was to minimize or eliminate the source of lamp breakage and once broken, to promptly replace the lamp.

The Commissioner agrees that the suggested means is quite obvious, but it is not always possible to eliminate lamp breakage and a damaged lamp can be replaced promptly only if it is identified quickly; reports indicate that damaged lamps are usually not found until people report injuries. Moreover, the agency does not have clearly defined authority either to require the use of shields to protect lamps against breakage, or to require the replacement of damaged lamps. Therefore, the Commissioner has concluded that, though prompt replacement of the damaged lamp is a good maintenance practice, it cannot be relied on as a dependable control of the radiation hazard.

3. Another comment suggested that mercury vapor lamps be prohibited from indoor use and that sodium vapor lamps, which are considered more efficient in producing light, should be used instead.

The agency, however, again does not have clearly defined authority to regulate the type of lamps which shall be used in a given facility. Nor does the Commissioner believe that the use of mercury vapor discharge lamps should be restricted, provided safe use of the product can be assured.

4. Many persons preferred a user education program rather than imposing product performance requirements. They argued that proper education of building and fire inspectors, maintenance and security personnel, along with lamp warning labels, can provide the same degree of protection as fail-safe lamps at a greatly reduced

cost and without a gross waste of energy.

The Commissioner agrees that an educational approach has merit and such an approach has been employed and will be continued, but it is not considered to be an adequate substitute for the engineering safety improvement of the product. Furthermore, there has been insufficient information submitted to support the argument that the fail-safe lamp will result in a gross energy waste. The Commissioner considers the educational and engineering approaches complementary and believes that a better result will be obtained by combining these two approaches in the effort to protect the public health.

Regulatory Versus Voluntary Approach

5. Among those comments received that supported the development and promulgation of a Federal regulatory standard, there was some reservation about the applicability of the standard. Several comments agreed with the agency's intent to issue radiation performance criteria for mercury vapor lamps, without specifically expressing their preference for either mandatory or voluntary criteria. In contrast, a number of comments contended that the criteria should be voluntary to keep the inevitable cost to a minimum. One comment endorsed the idea of a regulatory approach provided there is no major economic impact, but the same comment observed that any severe economic impact resulting from the regulation could eventually be lessened or eliminated by converting to other types of high-intensity discharge lamps.

The Commissioner shares the respondents' concerns about the potential economic impact, but he is not convinced that the voluntary approach, if successful, would be less expensive.

6. Some comments suggested that, instead of promulgating a Federal regulation, the additional protection needed for certain applications could be provided by means such as local or State building or installation codes, enforced either at the State or local level or by the Occupational Safety and Health Administration. Other comments suggested that the proposal should be delayed, withdrawn, or left to ANSI for proper action.

The Commissioner believes that the safe use of a product largely depends on the safety inherent in the design and performance of the product. A Federal regulatory standard can require that a product protect against injury, and the standard would apply, if adopted, to all mercury vapor lamps imported into or manufactured in this country. The implementation and enforcement of such a standard, particularly those provisions concerning warning labels or advertising materials for lamps that are not self-extinguishing, will be consistent and effective through established procedures, such as reporting and recordkeeping requirements, issuance of policy guides by the agency to provide uniform interpretations of the regulation, inspection of products and quality control at the factory by FDA personnel, and through education and guidelines for safe use directed to purchasers, designers, and users. Therefore, the Commissioner has concluded that a regulatory standard for mercury vapor lamps should be promulgated under the authority of the Radiation Control for Health and Safety Act of 1968 and rejects the suggestions for delays, withdrawals, or other approaches to the problem.

Applicability of the Proposed Standard

The applicability of the proposed standard and the definitions used therein would be specified in proposed § 1040.30 (a) and (b) (21 CFR 1040.30 (a) and (b)), respectively. The Commissioner is proposing that the standard become effective 6 months after publication of the final rule to assure that self-extinguishing lamps are available at the earliest possible date.

Because several lamp manufacturers now market self-extinguishing lamps, the Commissioner believes that the proposed effective date is practical and will not impose an unreasonable burden on any lamp manufacturer.

7. Comments on the proposed radiation safety criteria in the October 8, 1976 notice questioned the meaning of the term "mercury vapor lamp." One comment said the term appears too broad and would include other efficient light sources containing mercury vapor such as high-pressure sodium, metal halide, and fluorescent lamps. Another comment expressed a different view, asserting that a definition should be so worded as clearly to include the metal halide lamps.

"Mercury vapor lamp" was not specifically defined in the October 8, 1976 notice. The Commissioner agrees the term is ambiguous and should be defined. Therefore, proposed § 1040.30(b)(1) defines a "mercury vapor lamp" to include metal halide and self-ballasted lamps that contain primarily mercury in the inner arc tube. Metal halide and self-ballasted types of high-intensity discharge lamps have similar physical structure and emission characteristics, and the Commissioner believes they could pose a similar radiation hazard to the public. The proposed definition, however, would not apply to high-pressure sodium lamps or fluorescent lamps because currently available information is not sufficient to identify a public health risk in the use of such products.

8. Several comments requested that FDA consider minimizing regulatory restrictions for lamps used with fixtures equipped with protective coverings or other means to eliminate any radiation hazard.

The Commissioner is aware that some protective shieldings, properly installed, may be able to minimize or eliminate the radiation hazard. But, he is not convinced that such shielding will protect against injury from UV radiation under all use conditions. The Radiation Control for Health and Safety Act of 1968 provides authority to issue radiation-safety performance standards for the manufacture of electronic products which emit radiation. These standards may include requirements upon manufacturers to provide warnings and other information to users to assure radiation safety. The Act, however, does not provide clearly articulated authority for FDA specifically to regulate the manner in which an electronic product subject to such a standard is used. And, in any event, because of the variety of luminaires and use conditions, it would neither be practical nor feasible to impose a standard on the lamp and luminaire combined. The Commissioner welcomes comments directed both to the question of legal authority to regulate product use, as well as to the reasonableness of such an approach. The Commissioner, of course, will encourage users to employ lamps with a self-extinguishing feature for all applications except those cases where the probability of extended human exposure to the UV radiation from a broken lamp is unlikely. Nevertheless, the proposed standard would not preclude or prohibit other means to assure the safe use of mercury vapor lamps.

9. One comment suggested that the arc-extinguishing requirement be restricted to mercury vapor lamps of 175 watts and above. The comment argued that the intensity of the UV radiation is much lower for lower-wattage lamps.

The limited data submitted by the respondent indicate that the relative UV intensity from a 75-watt lamp is only about eight times less than that from a 400-watt lamp. These data do not support the idea as expressed in the comment that the lower-wattage lamps are safe. The Commissioner notes that, owing to different installation conditions such as mounting heights and fixture types, radiation from a lower-wattage lamp can be just as hazardous at a closer exposure distance or for a longer period of exposure time. Further, because of the structural variations and different operating conditions, it is not uncommon for a lower-wattage mercury vapor lamp to emit radiation comparable to that from a lamp of higher wattage. Therefore, the Commissioner concludes it is inappropriate to exempt lower-wattage lamps from the provisions of the standard.

10. Another comment suggested that certain tubular-shape and parabolic-aluminized reflector types of mercury vapor lamps that are not intended for

general lighting should be exempted from the self-extinguishing requirement of the proposed criteria because it is unlikely that people will be exposed for extended periods of time.

The Commissioner recognizes that these types of lamps are basically intended for specific purposes such as building or landscape floodlighting and specialized optical applications. These lamps can, however, be used in applications other than those intended. Human exposure to unnecessary short wavelength UV radiation is still possible when the outer envelope of such lamp is broken. The Commissioner advises that the proposed standard would not require that all lamps self-extinguish, but the standard would require that lamps that do not meet this provision be properly labeled and contain clear warnings against any misuse.

11. Many comments contended that any standard should apply to indoor installations only, or conversely that outdoor lighting application be exempted.

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The Commissioner believes that to draw a distinction between indoor and outdoor applications oversimplifies the problem and does not allow for flexibility for different uses of the lamps. For example, residential street lighting is not necessarily less hazardous than the lighting of some unfrequented warehouse. The Commissioner believes that exposure duration is a more important factor than is site of use in evaluating the risk associated with these products. But he is persuaded that the previously proposed imposition of the standard on all mercury vapor lamps for all applications is not necessary. He has, therefore, accepted the concept of two types of mercury vapor lamps: One that would be self-extinguishing and one that would not be, and he has incorporated this concept into this proposal by providing separate requirements in § 1040.30 (d) and (e). Adequate safety warnings would be required on packaging and in advertising for lamps that are not self-extinguishing. The effectiveness of this approach would depend on the understanding and cooperation of the purchaser and user, particularly those who are responsible for the installation and maintenance of the lamps. The Commissioner expects that a concerted effort on the part of manufacturers and FDA to increase the public's awareness of this problem and the potential liability of management personnel for injuries caused by improper use of lamps will reasonably assure proper use of the two types of lamps. However, the Commissioner welcomes any comment concerning the adequacy of the proposed two-lamp concept.

GENERAL REQUIREMENTS FOR ALL LAMPS

Proposed § 1040.30(c) would set forth the general requirements concerning certification and identification. Paragraph (c)(1) would require all high-intensity mercury vapor lamps to be permanently labeled or marked in such manner that the identity of the manufacturer and the month and the year of manufacture of the lamp can be determined even after the outer envelope is broken or removed. The required information may be expressed
in code or symbols provided the manu-
facturer has previously supplied the
Director of the Bureau of Radiological
Health with the key to such code o
symbols. For practical reasons, pro
posed § 1040.30(c)(2) would also permi
the manufacturer, in lieu of perma
nently affixing or inscribing tags o
labels on the product itself as require
by §§ 1010.2 and 1010.3 (21 CFR 1010.
and 1010.3), to place the required tag
or labels on packaging that is uniquel
associated with the lamp.

REQUIREMENTS FOR SELF-EXTINGUISHING LAMPS

Proposed § 1040.30(d)(1) would r
quire a self-extinguishing lamp to te
minate emission of short wavelengt
UV radiation that results from th
electric arc discharge between th
main electrodes of the lamp within
cumulative operating time not
exceed 15 minutes following lam
breakage. Section 1040.30(d)(1)(
would prescribe the breakage cond
tions on the effective date of t
standard, while § 1040.30(d)(1)(
would specify more restrictive brea

age conditions that apply 6 months after the effective date.

The Commissioner advises that the 15-minute cut-off time is based on consideration of biological effects, economic impact, and technical feasibility. Data presented by lamp manufacturers at the November 25, 1975 meeting between the staff of the Bureau of Radiological Health and ANSI's working group on mercury vapor lamps indicated that more than 93 percent of the lamps under test extinguished the arc tube within a period of 15 minutes. This is believed to be in the range of extinguishing time that will not affect either the structural integrity or the expected life span of the lamp. Thus, the economic impact of this requirement would be minimal. Bioeffects research data indicate, however, that a shorter cut-off time may be desirable, and lamp manufacturers have recently demonstrated that designing a lamp that would cease operation within a much shorter period following complete outer bulb breakage is feasible. Therefore, the Commissioner will reconsider and may modify this provision if life testing on such lamps shows that adverse effects on the reliability of the lamp is negligible, or the 15-minute termination time proves to be inadequate to protect the public from injury.

In defining complete breakage or removal of the outer envelope of the lamp, proposed § 1040.30(d)(1)(i) excepts fragments of the envelope that extend 50 millimeters or less from the base shell—this exception is made for consistency with ANSI's specifications for self-extinguishing lamps. The Commissioner has proposed this in an effort to avoid unnecessary conflict with the voluntary standard. But he advises that FDA has received reports of two separate incidents in which human injury resulted from UV radiation emitted through small holes in outer envelopes of high-intensity discharge lamps. Accordingly, he believes that self-extinguishing lamps must be required to extinguish when some fraction, substantially less than half, of the outer envelope is removed to adequately protect public health from these products when their mechanical integrity is violated and has so proposed in § 1040.30(d)(1)(ii). For consistency in compliance testing, a hole size corresponding to a continuous outer envelope surface area of 3 square centimeters has been chosen. The circumstances of the two incidents reported and the fact that in most cases, the arc tubes used in high-intensity discharge lamps are not completely exposed by a hole of such size provide some confidence that the hole size limitation is sufficiently small to provide health protection. At the same time, FDA tests of currently marketed self-extinguishing lamps indicate that such opening is sufficiently large to activate oxidizing shut-off mechanisms in conjunction with the other test conditions of the proposed regulation. Extension of the date for implementing § 1040.30(d)(1)(ii) 6 months beyond the date other provisions of the standard become effective will allow the manufacturers sufficient time to make necessary adjustments in their manufacturing procedures. However, he specifically invites comments on the differing criteria for breakage as well as the differing effective dates for establishing those criteria.

12. Several comments objected to the self-extinguishing lamp requirements. They contended that such design change would add cost to the consumer and would also result in added potential for premature lamp failure.

The Commissioner advises that, because FDA has adopted the two-lamp approach in this proposal, the self-extinguishing feature is no longer a requirement for all mercury vapor lamps. He believes that, for self-extinguishing lamps, the potential for premature lamp failure would be significantly reduced if the extinguishing time is permitted to be as long as 15 minutes. Although some increase in cost of manufacture may occur, such increase should be small and is justifiable for lamp applications of higher risk.

13. One comment stated that a self-extinguishing lamp can create a more serious hazard than the one it seeks to avoid because the arc tube of such lamp can remain electrically hot although it is no longer lighted. The

comment stated that a lighted arc tube would warn against direct contact.

The Commissioner considers the elimination of the unnecessary harmful UV radiation to protect the unaware public to be very important. Further, the electrical shock hazard that might be posed by an extinguished arc tube should be the same for self-extinguishing lamps and lamps that are not self-extinguishing. He therefore rejects the comment.

14. Some comments suggested that a special lamp with a keyed or special base be developed for indoor applications so that all new fixtures for indoor or similar applications would use a special socket, and the interchangeability of one type of lamp for another could be prevented by providing an adaptor for existing fixtures.

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The Commissioner recognizes the merit of a special base for certain types of application, but believes that the two-lamp approach in this proposed regulation makes this suggestion unnecessary. Because of the nature of usage of these lamps and the risk of management liability if installations do not employ safe lighting, the Commissioner has tentatively concluded that the suggested special base requirement is not needed. He does, however, welcome comments on this point.

Proposed § 1040.30(d)(2) would require the self-extinguishing type of lamp to be labeled with the letter "T" both on the base and the outer envelope of the lamp. Proposed § 1040.30(d)(3) would specify the labeling requirement on lamp packaging, including the display of the letter "T," and a statement regarding the self-extinguishing feature of the lamp and the risk of injury from operation of a damaged lamp.

REQUIREMENTS FOR NON-SELF-EXTINGUISHING LAMPS

Proposed § 1040.30(e) would require manufacturers of non-self-extinguishing mercury vapor lamps to provide identification labeling on both the lamp and lamp packaging. In addition, warnings concerning the risk of acute skin and eye injury and long-term effects such as cancer from exposure to UV radiation emitted by damaged lamps would be required on lamp packaging and in all advertising materials for such lamps. Included in the warning statement is a recommendation not to use these lamps in applications where excessive human exposure is likely to occur.

The term "excessive human exposure" is difficult to define quantitatively because injury potential depends upon a number of factors including the shielding of the lamp, the wattage and mounting height of the lamp, the duration of exposure to the radiation, and the skin sensitivity of the exposed individual. However, reports of injury received by the Bureau indicate that the use of this type of lamp in areas not routinely occupied by people, such as most street lighting and outdoor area lighting, does not result in excessive human exposure.

15. Comments were received supporting the general concept of proper warning for the use of these lamps. Some comments suggested specific wording to be used for the label. One suggested that the sale of these lamps be restricted to utilities only. Another suggested that the lamp base be color-coded. Still another recommended that, for industrial applications, such lamps be tested and labeled with a minimum installation distance from potentially exposed employees.

The Commissioner has carefully considered these comments in the preparation of the proposed regulation. Suggestions that have not been accepted are believed to be either impractical or unnecessary as mandatory requirements. However, the proposal does not preclude the manufacturers from providing, in addition to that prescribed in the regulation, any other information that is helpful for the safe use of the product.

TEST CONDITIONS

Proposed § 1040.30(f) would prescribe the conditions of testing for compliance with the standard. The prescribed conditions are the direct result of modification of the test conditions as proposed in the agency's previously published radiation safety criteria for mercury vapor lamps based on comments received, the ANSI standard for such lamps, and other public health considerations.

Background information on the proposed standard is on file with the Hearing Clerk, Food and Drug Administration. Included is a documentation report that provides a summary of the rationale for the technical requirements of the proposal. In addition, a copy of each of the references cited in the report is on file.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Public Health Service Act of 1968, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263(f)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 1040 by adding new § 1040.30, to read as follows:

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§ 1040.30

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[FR Doc. 78-10792 Filed 4-20-78; 8:45 am]

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†1.2 Final Regulation—September 7, 1979

– 44 FR 52191 –

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

[Docket No. 76N-0383]

Mercury Vapor Lamps; Radiation Safety Performance Standard

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: This rule prescribes a radiation safety performance standard for high-intensity mercury vapor discharge lamps, including the metal halide type, that are designed, intended, or promoted for illumination purposes. The standard permits the manufacture of both self-extinguishing and non-self-extinguishing mercury vapor lamps. The standard requires each lamp to be properly labeled so that its type, manufacturer, and date of manufacture can be easily determined. The standard further requires that self-extinguishing lamps cease operation within 15 minutes after the outer envelope is broken to ensure that excessive human exposure to shortwave ultraviolet (UV) radiation is not likely to occur. The standard also requires adequate warning to be provided on packaging and in advertisements for the non-self-extinguishing lamp for the safe use of the product.

EFFECTIVE DATE: March 7, 1980, except that § 1040.30(d)(1)(ii) shall become effective September 7, 1981.

FOR FURTHER INFORMATION CONTACT:

George C. Jan, Bureau of Radiological Health (HFX-430), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of April 21, 1978 (43 FR 16997), the Food and Drug Administration (FDA) proposed to establish a radiation safety performance standard for high-intensity mercury vapor discharge lamps. These lamps emit potentially harmful shortwave UV radiation if they continue to operate following breakage of the outer envelope. The public in general is not aware of this potential radiation hazard associated with the use of these lamps. The agency believes that the safe use of a product depends largely on the safety inherent in the design and performance of the product, and a regulatory standard for such products is needed to protect the public health and safety. Interested persons were given until June 20, 1978 to file written comments on the proposal.

A total of 12 comments were received—4 from manufacturers, 5 from utility companies and user groups, 2 from private citizens, and 1 from a national association of manufacturers. These comments and the agency's conclusions are summarized as follows:

1. One comment stated that the proposed standard had already created shortages in supplies for replacement because manufacturers had stopped making replacement lamps for fear they could not sell them.

No documentation was provided to substantiate the claim made in this comment. The standard permits two types of mercury vapor lamps: Self-extinguishing and non-self-extinguishing. The former now represents only a small percentage of all mercury vapor lamps sold. This agency has not received a report from any manufacturer that it plans to discontinue the manufacture of non-self-extinguishing lamps, nor has the agency received any report of a supply shortage of this type of lamp from users such as utility companies. FDA believes that the manufacture of mercury vapor lamps will be continued as long as they are needed and their use is not prohibited.

2. One comment said that the FDA's failure to set forth guidelines for recall in the proposal creates confusion. This omission leaves manufacturers of self-extinguishing mercury vapor lamps open to second-guessing situations for substantial and unnecessary risk of recall. The comment suggested that FDA should offer guidance in quality control to help prevent the introduction of defective lamps into the marketplace.

The standard requires that all mercury vapor lamps, not just a portion of them, comply with the standard. Regulations regarding the determination of noncompliant or defective electronic products and the repair, replacement, or refunding the cost of such products under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602; 82 Stat. 1173 et seq.) have been issued (see Parts 1003 and 1004 (21 CFR Parts 1003 and 1004)). In exercising its authority under Part 1003 to determine that a product has a defect or fails to comply with an applicable standard and to require that notification be made to dealers, distributors, and purchasers, the agency may take into account such relevant factors as the nature, extent, and cause of the defect or failure of compliance. If a final determination has been made that a product has a defect or fails to comply with a standard and the manufacturer has not been granted an exemption from notification and repair (§ 1003.31 (21 CFR 1003.31)), the manufacturer would be required to repair, replace, or refund the cost of the defective on noncompliant product.

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Certification of compliance may be based on a testing program that is in accordance with good manufacturing practices, provided it has not been disapproved by the Director, Bureau of Radiological Health, on the ground that it does not ensure that the products comply with the standard. The agency does not intend to prescribe the use of a specific testing program or specific sampling plan because a number of different testing programs could be adopted to ensure compliance. FDA's policy, however, is to issue compliance testing guidelines before the effective date of the standard to assist industry in establishing adequate testing programs. It should be pointed out that the disapproval of a testing program does not by itself result in the need for product recall. A finding that manufactured products have defects or fail to comply with an applicable standard is required before proceedings under Part 1003 could be initiated by FDA. The agency believes this response to the comment will eliminate any confusion as to the circumstances under which recall of defective mercury vapor lamps would be required and will demonstrate that additional guidelines or regulations are not needed.

3. One comment contended that the implementation of the regulation as proposed would constitute a disservice to the general public, be contrary to the President's stated goal of easing the burden of Federal regulations, and amount to a breach of faith on the part of FDA toward the Technical Electronic Products Radiation Safety Standards Committee (TEPRSSC) and the lighting industry. The comment

urged that FDA subject the regulation to the review and analysis procedures prescribed in Executive Order 12044.

The agency disagrees that implementation of the proposed performance standard would either constitute a disservice to the general public or be in conflict with the President's goal. On the contrary, in the interest of the public health, it is essential that mercury vapor lamps be designed to terminate emission of shortwave UV radiation after breakage of the outer envelope or, if the lamps are not so designed, that the purchaser and user be warned of the potential danger of the lamps. The agency is convinced that the public interest is best served by a mandatory standard.

In the development of this standard, FDA has consulted with the lighting industry and has kept TEPRSSC aware of the course the agency was taking. In fact, during the May 6, 1977 meeting of TEPRSSC, the Bureau of Radiological Health informed the Committee that FDA intended to publish a proposed regulatory standard that would provide for both self-extinguishing and non-self-extinguishing lamps, and that the extinguishing time might have to be lengthened from the previously proposed 2 minutes because of the need for lamps to self-extinguish following partial lamp breakage as well as complete breakage. The Committee did not object to this course of action.

Concerning review and analysis pursuant to the Executive Order, it is not completely clear what review and analysis procedures the comment refers to. If it means "regulatory analysis" as described in Section 3 of the Executive Order, then this type of analysis is required to be applied only to significant regulations that have major economic consequences. According to FDA's interim guidelines for the implementation of Executive Order 12044, a regulatory analysis is required if the regulation would cause either (1) an increase in total cost or price of goods or services to the national economy of $100 million in any 1 year, or (2) an increase in cost or price of goods or services of 10 percent in any 1 year in any industry or market, level of government, or geographic region, provided that the increase in cost or price of goods or services so affected exceeds $10 million annually. The economic impact assessment for the proposed mercury vapor lamp standard and its supplement as filed with the FDA Hearing Clerk indicate that neither of these criteria is exceeded. Therefore, a regulatory analysis for the mercury vapor lamp standard is not needed. However, the background documents, including the documentation report, the environmental impact analysis report, and the economic impact assessment and its supplement for this standard, in the FDA Hearing Clerk's file contain most information required by the agency's guidelines to be provided in a regulatory analysis.

The supplement to the economic impact assessment was prepared because of concern expressed by some TEPRSSC members about the cost effectiveness of the standard after it was published as a proposed rule in the FEDERAL REGISTER. The additional cost for self-extinguishing lamps was estimated in the supplement to be $2 to $5 million each year and was expected to decrease to a level of $1 to $2 million within 4 years after the standard goes into effect. Based on available data and conservative assumptions, FDA obtained an acceptable benefit/cost ratio for the standard.

4. One comment noted that, without a clear knowledge of the distance/duration/intensity characteristics of UV radiation emitted by a lamp and the likelihood of breakage of the outer lamp envelope, the user of lamps for outdoor applications is at a loss to determine which type of lamp to use. This comment suggested that FDA should offer the user specific guidelines and recommendations as to which types of installations the agency considers safe for the use of the standard non-self-extinguishing lamps.

Use conditions for lighting installations vary. Thus, the agency believes that it would be impractical to provide, in the form of labels and advertisement statements, detailed guidelines for when or where a non-self-extinguishing lamp should be used. However, educational materials for the use of mercury vapor lamps were developed and issued by this agency in November, 1977 (HEW Publication No. (FDA) 77-8041), containing some general recommendations and guidelines for the safe use of the product. These educational efforts will be continued and broadened in the future.

5. One comment argued that shielding of other radiation sources can be regulated and that the same authority could extend to mercury vapor lamp fixtures. According to this comment, adequate shielding still appeared to be the most straightforward, practical, and least costly solution to the problem.

Because fixtures for mercury vapor lamps are generally considered to be separate devices and are sold separately, it would be impractical to impose a standard on the lamp and fixture combined. The agency recognized the merit of adequate shielding and in the November 1977 Consumer Memo recommended it as a way to provide protection against the potentially hazardous radiation from existing lamps. The standard also permits adequate shielding as an alternative to the use of self-extinguishing lamps (§ 1040.30(e)(2)(ii) (21CFR 1040.30(e)(2)(ii).) However, regulating the fixture when the problem is associated with the broken lamp is inappropriate. Further, FDA does not agree that shielding is the most straightforward, practical, and least costly solution. For certain lighting applications where the amount of light output is critical for the performance of the intended function, the use of shielding may not be desirable. Also, the installation of a protective shield, even if it is possible depending on the type of fixture, is not necessarily less expensive than a self-extinguishing lamp. The agency believes that the public would benefit more from a choice to suit a particular need than from being unnecessarily burdened with a mandatory requirement for shielding. This approach is also consistent with the President's stated policy in Executive Order 12044 to minimize compliance costs and other burdens on the public.

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6. Several comments contended that the regulatory approach would impose additional and unnecessary costs without giving the public more protection against injury. They believed that the current American National Standards Institute (ANSI) standard (C78-1330-1976, Specification for Mercury Lamps with Integral Means for Extinguishing the Arc after the Outer Envelope is Broken) is adequate to protect the public and should be adopted as a nonregulatory guideline for designing self-extinguishing mercury vapor lamps. One comment recommended that the ANSI standard be adopted with a change in the extinguishing time limit from 2 minutes to 15 minutes. Two comments suggested that the voluntary approach be coupled with an effective educational effort by both FDA and the lighting industry.

The agency is not convinced that a successful voluntary approach would be less expensive to the lighting industry, FDA, and consumers than a regulatory approach. The effectiveness of a voluntary standard depends on both FDA's and industry's programs to monitor and assure compliance. Such programs would include keeping relevant manufacturing and distribution records, preparation of reports on product safety, and adequate quality control and testing. FDA does not agree that the costs of a regulatory standard would be unnecessary or would not provide the public more protection.

In contrast to the proposed Federal performance standard, the ANSI standard does not provide for warnings in advertisements that non-self-extinguishing lamps should not be used in applications where potential acute injury to the eyes and skin from broken lamps is likely to occur. Nor does the ANSI standard require that lamps self-extinguish in the event of partial breakage of the outer envelope. The agency believes that such warning to potential purchasers and self-extinguishing lamp characteristics are essential for protection of the public health.

7. Two comments objected to subjecting all lamp types of different wattages to the proposed requirements

and suggested that applicability to a few higher wattage lamps, e.g., those over 175 watts (W), is all that is necessary.

The preamble to the April 21, 1978, proposal noted in part: "Owing to different installation conditions such as mounting heights and fixture types, radiation from a lower-wattage lamp can be just as hazardous at a closer exposure distance or for a longer period of exposure time. Further, because of the structural variations and different operating conditions, it is not uncommon for a lower wattage mercury vapor lamp to emit radiation comparable to that from a lamp of higher wattage." The agency, therefore, concluded: "It is inappropriate to exempt lower-wattage lamps from the provisions of the standard." This conclusion still remains valid in the absence of new data, and the comments are rejected.

8. One comment asked the meaning of the term "extended human exposure" and the use of a lamp in which extended human exposure to the short wave-length (UV) radiation from a broken mercury vapor lamp is considered unlikely. Other questions raised in the same comment were concerned with the concept of unacceptable exposure duration and the effect of the type of fixture or the mounting height on its likelihood of causing excessive human exposure.

Extended human exposure involves the concept of duration of exposure and would generally be considered unlikely in lighting applications such as roadway, street, and area lighting, and others where people do not remain under the light for a long time. The duration of exposure would usually be short enough to preclude injury. Excessive human exposure should be thought of in terms of total quantity of exposure that would result in human injury. Total quantity of exposure is the product of exposure duration and radiation intensity. Because the type of fixture and its mounting height can affect radiation intensity, they should be given careful consideration along with other factors, such as the intensity of the light source, in evaluating the likelihood of causing excessive human exposure. For example, a lamp would be less likely to cause excessive human exposure if mounted at a height of 40 to 50 feet than if mounted at a height of only 10 feet. The agency agrees, however, that the meaning of the term, "excessive human exposure" as contained in the proposed warning statements for non-self-extinguishing mercury vapor lamps was not sufficiently precise, and, therefore, the warning statements (§ 1040.30(e)(2)(ii) and (3)) have been revised to delete the term and make clear that such lamps should not be used where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used.

9. One comment expressed concern about the use of mercury vapor lamps for nondestructive material testing such as inspection for the existence of porosity or cracks in a metal surface by exposing the test surface under near UV light from a mercury vapor lamp. The comment claimed that it makes little difference in the application whether the lamp envelope is damaged if the filter and the housing containing the lamp remain intact and in place. Therefore, use of a self-extinguishing type of lamp in this case would be an "expensive nuisance." Use of the non-self-extinguishing type would also constitute a violation of the letter of the required label warning against use of such lamps in applications where excessive human exposure is likely to occur because the term "excessive human exposure" could also mean near UV radiation to which inspecting personnel are likely to be exposed in this application.

The agency notes that the standard does not apply to mercury vapor lamps that are not designed, intended, or promoted for illumination purposes. The agency advises, however, that (§ 1040.30(e)(2)(ii) and (3)) has been revised to clarify that the warning statements refer only to shortwave UV radiation.

10. One comment suggested that the regulation should not apply to mercury vapor lamps that include an optical assembly, such as an aluminum reflector

with a glass refractor completely enclosing the lamp that absorbs the shortwave UV radiation given off by a broken lamp.

The standard is intended to apply to the mercury vapor lamp only, not the lamp and fixture combined. The difficulty of treating the lamp and fixture combined as a single product has been discussed. The agency rejects the comment because a non-self-extinguishing lamp can be used under the circumstance described without violating the spirit or intention of the warning label.

11. Several comments suggested that the definition of "high-intensity mercury vapor discharge lamp" in § 1040.30(b)(1) be modified to exclude the self-ballasted type. They claimed that self-ballasted mercury lamps are fundamentally different from the standard mercury vapor lamp and have never caused a radiation burn incident. The mercury arc tube of a self-ballasted lamp is wired electrically in series with an incandescent, tungsten filament that is absolutely necessary to the functioning of the lamp and also serves as an inherently quick self-extinguishing device. Further, the total lamp wattage of the self-ballasted type lamp is divided so that, for the range of 160-W to 1250-W lamps, arc tube wattage dissipation is only about 25 to 50 percent, respectively, of the total wattage. Compared with equal wattage standard mercury vapor lamps, this design principle also results in nonsimilar mercury spectral emission properties.

A few comments also urged that metal halide lamps be excluded from the provisions of the standard. The comments contended that the quantitative characteristics of mercury vapor lamps and metal halide lamps are quite different. They argued that metal halide arc-tubes, under the same conditions of wattage and operating parameters with the envelope removed, emit less UV radiation below 320 nanometers (nm) by a factor of at least 6 than that of mercury vapor lamps. The comments also argued that extinguishing mechanisms could not arbitrarily be introduced into metal halide lamps with the anticipation of their being equally effective. In the absence of incidents due to this type of lamp, the comments considered the inclusion of metal halide lamps in the definition unwarranted.

The agency agrees to exclude from the definition of high intensity mercury vapor discharge lamps the tungsten filament self-ballasted type that extinguishes quickly in case the outer envelope of the lamp is broken. Because of this inherent safety feature, overexposure to shortwave UV radiation emitted from a broken lamp of this type is unlikely to occur. Section 1040.30(b)(1) is revised accordingly.

However, metal halide lamps have physical structure and emission characteristics similar to those of mercury vapor lamps. Sufficient shortwave UV radiation is emitted by broken metal halide lamps to lead to the conclusion that these radiation levels are capable of causing injury. Thus, the agency concludes that metal halide lamps should either be self-extinguishing or carry the proper warnings as required in the standard and rejects the comments.

12. One comment objected to the requirement that non-self-extinguishing lamps be marked with identification codes that would be visible after the envelope was broken. Because these lamps contain no safety device, extra labeling is not needed, is an unnecessary expense to the industry, and serves no purpose.

Identification of the manufacturer and date of manufacture is necessary for any electronic product subject to a standard. Because injuries from these products can occur when the lamp is broken, it is necessary to be able to identify the manufacturer and date of manufacture after the bulb is broken and to be able to investigate labeling, sales, and advertising practices. The comment is rejected and the labeling requirement of § 1040.30(c)(1)(ii) is retained.

13. Several comments contended that merely extending the time permitted for a lamp to self-extinguish from 2 to 15 minutes to ensure that a lamp shuts off when punctured but not broken was not justified. They claimed that this trade-off seemed unnecessary in view of the low incidence

and uncertainty concerning reports involving small holes in the outer envelopes of mercury vapor lamps. Further, to provide for automatic cutoff in the event of a small hole in the lamp envelope would require a costly program to develop a new design that was not warranted by such a highly improbable occurrence. Some comments urged that the compliance date for partial breakage be extended to allow additional time to develop and test adequate self-extinguishing mechanisms.

More than 60 persons were reported injured in a single incident of partial breakage of the outer envelope of a mercury vapor lamp. This alone is sufficient to cause concern for similar incidents regardless of the frequency of such occurrences. Preliminary laboratory tests by FDA also show that partial breakage of the outer envelope of mercury vapor lamps is readily produced when the envelope is struck by a pellet from a low velocity air rifle. The agency believes that it is necessary to provide a shutoff mechanism in the lamp to avoid injuries when partial breakage occurs in the outer envelope. The 15-minute cutoff time, however, is not based solely on the need to protect against the occurrence of partial breakage of the lamp. The 15-minute cutoff time is believed to be a reasonable limit that would provide more flexibility for lamp design without sacrificing the intention to reduce the probability of injury effectively. However, to allow sufficient time for manufacturers to perfect their lamp designs and complete testings of the products under various breakage conditions, the agency agrees to extend the compliance date of the provision of § 1040.30(d)(1)(ii) until September 7, 1981. This extension of the compliance date would further alleviate any economic impact.

14. There was also some concern about the extra energy consumption of self-extinguishing lamps that use a tungsten fuse to satisfy the partial breakage condition requirement in the standard.

A power loss of about 12 W in the tungsten coil of a 400-W lamp was reported by a manufacturer of such lamps. This represents approximately a 3 percent lower lamp efficiency. The reduction in luminous efficiency for other lamps with different wattage ratings is not known to FDA at the present time. The reduced efficiency for 400-W lamps is too small to affect the intended function of the lamps for general illumination. The estimated reduced efficiency is also small when compared with the acceptable lamp lumen depreciation (LLD) factors specified over the useful life of the lamp, and with the inherent lamp-to-lamp variation in radiation emitted. Because the total light reduction is small and the energy consumption for the operation of a single lamp remains the same for the same wattage lamp, FDA believes that there would be little, if any, extra energy consumption from the use of such lamps. Thus, no change in the regulation is necessary.

15. One comment suggested that the proposed "T" or "R" marking on the lamp base is unnecessary because the lamp or mount remaining in the event of breakage can be identified by its manufacturer; because the surface area of the base available for such a marking is very limited; and because the marking would tend to become obliterated during lamp life. Further, making the base would require an extra production step as well as segregation of base inventories prior to cement filling. Another comment considered additional "R"marking other than those required in ANSI's standard on lamps without a safety device confusing and unnecessary.

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Because of these comments, the agency has reconsidered the requirement for locating the "R" or "T" marking on the base of the lamp. The requirement is intended to provide a means to identify quickly and readily any lamp subject to the standard in the event the outer envelope of the lamp has been broken away. Further, because the standard permits two types of lamps to be marketed, the ability to distinguish unambiguously one type from another in all cases is critical for the effective implementation and enforcement of the standard. The agency believes, however, that the intent of the proposed requirement would not be compromised if the markings were permitted to be located on any part of the lamp, provided they are clear and prominent whether the lamp is intact or the outer envelope broken or removed. The agency has, therefore, modified § 1040.30 (d)(2) and (e)(1) to provide the manufacturer with greater design flexibility with regard to the location of these markings. The agency, however, disagrees that additional "R" marking, other than the warning statement required in ANSI's standard on non-self-extinguishing lamps, would be unnecessary and cause confusion. On the contrary, FDA believes the "R" marking will help in identifying the lamp type directly, especially when the outer envelope of the lamp is broken or removed.

16. One comment considered the word "damaged" used in the warning statements not sufficiently precise. It suggested that the exact type of damage, namely, the broken outer envelope, be expressly referred to in those statements.

The agency agrees that the word "damaged" used in the proposed warning statements was not precise. Section 1040.30(e) (2)(ii) and (3) has been revised as suggested in this comment.

17. Several comments objected to the inclusion of the word "cancer" in the proposed warning statements. Reasons cited for this objection include: The lack of scientific evidence that cancer can result from an accidental one-time exposure to radiation from a broken mercury vapor lamp; such an exposure represents an extremely small fraction of an individual's lifetime burden of UV radiation; and the proposed wording goes beyond the contents of FDA's own recommended labeling for UV generators (§ 801.403 (21 CFR 801.403)), misleading the general public with regard to the hazard from broken mercury vapor lamps and constituting a violation of the agency's misbranding regulations. In general, these comments contended that the proposed labeling exaggerated and overemphasized the potential hazard of broken mercury vapor lamps.

The agency is concerned that even a single severe overexposure to shortwave UV radiation may increase an individual's risk of developing skin cancer. The greatest concern with shortwave UV radiations inducing skin cancer, however, is the effect of repeated overexposure. In this respect, the proposed warning may unnecessarily alarm the public, because repeated exposures to UV radiation from broken mercury vapor lamps would be unusual in the normal use of those products. Therefore, the reference to cancer has been deleted from the warning statements required by this final rule. The agency believes, however, that there is need to warn individuals, such as maintenance personnel, whose occupation would result in repeated exposures to UV radiation from broken mercury vapor lamps, and will take appropriate steps to disseminate this information.

18. A summary of significant comments as discussed in this preamble was also presented at the 17th meeting of TEPRSSC on November 9, 1978. Significant oral comments and recommendations made by members of TEPRSSC and representatives from industry attending that meeting were repeated in writing and have been carefully considered and responded to throughout this notice.

19. In addition to all comments received, the agency notes that proposed § 1040.30(d)(1), regarding the effective dates for compliance with the maximum cumulative operating time and size of the hole provisions was unclear. Section 1040.30(d)(1) (i) and (ii) has been modified in the final rule to make clear when each requirement is effective.

Also, for clarification, the agency has added a definition for "reference ballast" to the standard. Section 1040.30(b)(8) identifies this component as an inductive reactor with the operating characteristics listed in the appropriate section of ANSI C 82.5-1977.

Finally, the agency is also modifying the warning statements of proposed § 1040.30(e) (2) and (3) to ensure that users and lamp purchasers are informed of the availability of self-extinguishing lamps.

To reduce the potential hazard from mercury vapor lamps by subjecting them to the radiation safety performance requirements of the standard at the earliest possible date, this standard shall become effective March 7, 1980, except for the requirements in § 1040.30(d)(1)(ii) pertaining to punctured lamps. Because several lamp manufacturers now market self-extinguishing mercury lamps that they claim meet either the complete breakage or complete and partial breakage test conditions as required in § 1040.30(d), the agency believes that the effective date of the standard will not impose an unreasonable burden on any lamp manufacturer.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 1040 is amended by adding new § 1040.30 to read as follows:

* * * * *

§ 1040.30

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[FR Doc. 79-27213 Filed 9-6-79; 8:45 am]

G. Sunlamps

1.—Performance Standards

†1.3 Final Regulation—November 9, 1979

- 44 FR 65352 -

PART 1002—RECORDS AND REPORTS

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

[Docket: No. 75N-0047]

Sunlamp Products; Performance Standard

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: This rule establishes a performance standard for sunlamp products and ultraviolet lamps intended for use in these products. The standard is intended to reduce the possibility of sunlamp-related injury by reducing unnecessary exposure and overexposure to sunlamp radiation by: (1) Limiting shorter wavelength emissions that are unnecessary and pose unreasonable risk, (2) providing for more adequate label warnings and user instructions containing safety information, and (3) requiring special lamp bases, protective goggles, timers, and controls to help users limit the duration and amount of exposure. A sunlamp product would be subject to these requirements if it is an electronic product designed to use one or more ultraviolet lamps (bulbs) and is intended for irradiation of any part of the living human body by ultraviolet radiation within a specified range of wavelengths to induce skin tanning. Ultraviolet lamps subject to the standard are those which produce radiation within a prescribed range of wavelengths and are intended for use in sunlamp products.

EFFECTIVE DATE: May 7, 1980, for sunlamp products that are manufactured on or after this date.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of December 30, 1977 (42 FR 65189), the Food and Drug Administration (FDA) proposed to establish a radiation safety performance standard for sunlamp products due to a recognized need for a regulatory standard for such products to protect the public health and safety. Interested persons had until February 28, 1978, to file written comments on the proposal. Comments were received from at least 214 different sources: 169 individuals, 26 physicians and medical facilities, 11 medical associations and their chapters, 9 manufacturers, 4 governmental agencies, a manufacturer's association, an equipment rental association, a spa owner, a retail sales company, and an independent quality control laboratory. Also, there were four congressional inquiries.

A summary of the comments and the agency response are as follows:

1. Several comments expressed the idea that the safety performance standard is needless, ineffective, costly, and an unwarranted government intrusion. Others maintained that: (1) Most sunlamp products already come with adequate warnings, (2) the public is already aware of ultraviolet radiation hazards, and (3) only those who are careless are injured by sunlamp products.

That there is a radiation problem with sunlamps is shown by the large number of sunlamp-related skin and eye injuries treated annually in hospital emergency rooms. This number does not include injuries treated outside the hospital or any long-term effects, such as skin cancer. FDA has considered the increased costs that a performance standard may impose on manufacturers and, therefore, on consumers of sunlamp products, and is convinced that the costs are outweighed by the increased safety that will result from the standard. (See the economic impact assessment that accompanied the proposed regulation.) Furthermore, changes introduced in the final rule will reduce the cost of complying with the standard.

The standard for sunlamp products is being established to protect the consumer from acute burns (as evidenced by erythema) and exposure to unnecessary, hazardous radiation (in this case, ultraviolet C), and to warn the consumer of the adverse effects to the body after exposure to ultraviolet radiation. A consumer can take appropriate action: (1) When informed of the possible adverse effects to the body of exposure to ultraviolet radiation, and (2) when the product is provided with necessary safety performance features. The safety information and performance features on the product may be ineffective when a person is careless. However, the agency believes sunlamps perform a function desired by the consumer and, consequently, has not penalized the prudent individual by removing this potentially hazardous product from the marketplace.

2. Several comments objected to the standard's proposed early effective date of only 30 days after the date of publication of the final rule. Some objections were based upon the technical problems associated with the redesign of products; others were based on the technical, logistic, and personnel problems of manufacturing sunlamp products that would comply with the standard. Also, a manufacturer claimed that, because its sunlamp product now conforms to the provisions of the proposed rule, the urgency for the early effective date has been eliminated.

The agency agrees with the intent of these comments and defers the effective date of the standard to 180 days after the date of publication of the final rule. The effective date has not been deferred to more than 180 days after the date of publication because many companies have already redesigned many aspects of their products to meet the standard and because the high injury rate continues.

3. A comment stated that there are millions of existing sunlamps now in use that require medium screw base replacement bulbs. Those manufacturers who are marketing Underwriter Laboratories, Inc., listed products have already changed (since 1975) to designs requiring other than medium screw bases. For the older devices, however, an immediate cut-off of replacement lamps would seem an unfair economic burden to the owners. A reasonable approach would be to defer the effective date of this portion of the standard for 12 to 18 months.

The agency notes that products manufactured before the effective date of an applicable regulation would not be subject to that regulation. Replacement lamps for old products can be manufactured until the effective date of the standard and may be sold thereafter until the supply is exhausted. Further, the effective date of the standard is being deferred to 180 days after publication of the final rule.

4. One comment concerned the length of time a sunlamp must comply with the performance standard. The comment stated that experience confirms that timers and other parts of the sunlamp may fail prematurely because of faulty design, and, therefore, manufacturers should provide FDA

with reasonable assurances of the reliability of the timers and other components used in their products.

The agency notes that the manufacturer of a radiation emitting electronic product subject to a performance standard is required to certify to the purchaser that the specific product being purchased complies throughout the useful life of the product with the applicable requirements of the standard in effect at the date of manufacture. The manufacturer must also develop a suitable quality control program and assure the FDA of compliance through reports describing the product and the quality control program. In addition, the agency has a program of inspecting the manufacturing facilities for regulated products.

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5. One comment objected to the introduction of the language, "or otherwise affect the function of the body," and the specific exclusion of prescription ultraviolet products from the proposed definition of "sunlamp product." The comment argued that this changes the standard substantially from one only for sunlamps used for skin tanning. Furthermore, the comment objected to the classification, or at least implication of classification, of sunlamp products as medical devices, and it objected to applying Part 801 (21 CFR Part 801) to such products until they have been properly classified in accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c), added by the Medical Device Amendments of 1976 (Pub. L. 94-295).

The agency accepts a portion of this comment because the standard was developed specifically for sunlamps used in skin tanning and may not be appropriate for ultraviolet devices intended for other applications, e.g., cabinets used exclusively for psoriasis treatment. Therefore, the definition of "sunlamp product" in § 1040.20(b)(9) is revised to delete the language "or otherwise affect the structure or any function of the body" and the reference to Part 801. The agency believes sunlamp products are medical devices because the various therapeutic uses for sunlamp products, including treatment of fungal diseases, vitamin D production, treatment of psoriasis, and treatment of acne, cannot be readily separated from the tanning function insofar as assurance of intended use and danger from overexposure are concerned. Thus, the references to Part 801 in § 1040.20(b)(1) and (d) are retained.

The agency notes that the last sentence in proposed § 1040.20(b)(9) identifying uses not covered by the definition of "sunlamp product" is not needed to clarify the definition and, therefore, also deletes it in this final rule.

6. Several comments questioned the appropriateness of applying the standard to the sunlamp facilities installed in gyms, health clubs (spas), and other similar commercial establishments, where conditions of operation vary widely. For example, the comments alleged that timers are unnecessary when trained attendants are present or ineffective when more than one person is using the sunlamp facility at the same time. One comment recommended that commercial facilities be encouraged to hire attendants rather than rely on timers or customers to follow posted instructions. One national health club stated that virtually none of its sunrooms conforms to the proposed standard and that extensive and expensive modifications would be necessary to bring these facilities up to the standard. The comment explained further that, in most cases, there are no timers, no devices to interrupt manually the sunlamp operation, no user instructions, and no protective eyewear. Furthermore, the comment stated, the club is considering removing the sunlamp facilities from use until it is sure the facilities are safe to prevent any liability through noncomplying equipment.

The agency believes that, in the interest of the public health, the standard should apply to any sunlamp product meeting the definition of § 1040.20(b)(9), including those in use in commercial facilities. The agency has, however, considered the various requirements of the final rule as applied to these suntanning facilities, and to sunlamp products generally, and has concluded that the timer requirements of § 1040.20(c)(2) may be inappropriate in some circumstances. Upon application by the manufacturer, other means for providing radiation safety or protection may be approved in accordance with procedures in § 1010.4 for granting variances.

FDA advises that only sunlamp products, including commercial suntanning facilities, manufactured after the effective date of the final rule will be subject to the standard. Thus, owners of existing commercial suntanning facilities need not modify their facilities to comply with the standard, although they are encouraged to do so. Also, because in response to another comment the agency has concluded that fluorescent ultraviolet lamps may continue to be designed to fit the medium bipin lampholder, no retrofit programs by the commercial suntanning facilities will be necessary to accommodate the available replacement lamps (see comment 14). Some changes in procedures may be needed to ensure the availability of eyewear and the availability of information about the hazards associated with exposure of the body to ultraviolet radiation. These changes will make the facilities safer but not completely safe, because there may be no safe threshold level for exposure to ultraviolet radiation.

7. Some comments objected to the irradiance ratio of 0.001 in § 1040.20(c)(1). One objection was on the ground that the manufacturer had attempted and failed to design an efficacious bare quartz lamp that would meet this requirement. Another manufacturer claimed that the ultraviolet radiation in the wavelength range of 200 through 260 nanometers (nm) is less hazardous than the radiation in the wavelength range of 260 through 320 nm. It was stated that, because the latter is allowed, the former need not be restricted too much, and an irradiance ratio of 0.02 should be adopted.

The agency declines to raise the irradiance ratio on the basis presented in these comments. The radiation in the wavelength range of 200 through 260 nm is known to be hazardous and is not necessary for skin tanning. Available data on terrestrial solar irradiances indicate that radiation of that wavelength range emitted by the sun does not reach the earth. The relative safety of the ultraviolet radiation of the wavelength range from 260 through 320 nm is not the issue. The fact is that ultraviolet radiation in the shorter wavelength range is both hazardous and unnecessary for skin tanning, and, therefore, exposure to it should be reduced.

8. A comment recommended the adoption of 0.003 as the irradiance ratio in § 1040.20(c)(1) to take into account product variability and uncertainties in irradiance measurements for quality control in the manufacturing environment.

FDA agrees. Achievement of an exact ratio of 0.001 is not easy. Product variability and uncertainties of measurement of irradiance ratios render achievement of the 0.001 irradiance ratio difficult. Because many presently available sunlamps are close to the 0.001 irradiance ratio but not exactly at it, they would require substantial redesigning to lower their levels of ultraviolet radiation of wavelengths less than 260 nm. Achievement of a 0.003 irradiance ratio, however, is much easier for all concerned.

Also, the agency believes that the increase in the irradiance ratio will not compromise the protection afforded the public (1) because lamps that have little filtration for the ineffective ultraviolet radiation wavelengths less than 260 nm will still be prohibited; (2) because uncertainties in determining compliance will cause manufacturers to produce a product with a target irradiance substantially below 0.003; and (3)

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because the level of ultraviolet radiation of wavelengths less than 260 nm will be increased at most only 2 parts in 1,000 of the total ultraviolet emission. Furthermore, the cost of many sunlamps on the market will not be increased as a result of a necessary product redesign to meet the new irradiance ratio limit. For these reasons, the irradiance ratio is increased to 0.003.

9. A comment suggested that the irradiance ratio be abolished because it

does not accomplish the desired effect of limiting the integrated irradiance at shorter wavelengths to less than 0.1 millijoule per square centimeter (mJ/cm^2) or any other value that might be considered appropriate. The comment stated that, because the bioeffects literature shows that "0.1 mJ/cm^2 at 254 nm may have deleterious effects," the regulation should simply limit the permitted total integrated irradiance for all wavelengths less than 260 nm to less than 0.1 mJ/cm^2 within the maximum timer interval possibile for each sunlamp product. This eliminates specifying a maximum timer interval. The requirement of a timer that has a specified accuracy would still be relevant while the suggested change would permit the manufacturer to choose the rate at which its product achieves the desired tanning and should give the consumer a reasonable choice of products.

The agency agrees with the bioeffects literature; however, it rejects the conclusion because an upper limit to the integrated irradiance for the short wavelength ultraviolet only would require that each sunlamp product model have different ultraviolet radiation filtration and timer characteristics, depending upon the lamp brightness and distance of the user from the product. The irradiance ratio in § 1040.20(c)(1) would avoid these problems, provide greater design flexibility to manufacturers, and reduce the short wavelength range ultraviolet emissions. The irradiance ratio limit is intended only to limit unnecessary, hazardous radiation and is not to be understood as a biologically "safe" limit. A manufacturer is free to choose the rate at which the product achieves the desired tanning regardless of whether a specific irradiance limit for the ultraviolet radiation of wavelengths less than 260 nm or an irradiance ratio is chosen.

10. Several comments questioned how the 10-minute maximum timer interval was established and claimed that 10 minutes may be too much in some cases and too little in others. They stated that the warmup time should be defined as the time taken to reach a certain irradiance level and that the maximum timer interval should be increased by the warmup time. Also, they stated that the minus tolerance on timer accuracy was not needed and should not be required. Another comment was concerned that, because sunlamp manufacturers usually recommended a set of exposure distances and corresponding exposure times, the agency might regard the recommended exposure time for the shortest distance as the maximum timer interval.

The agency advises that the preamble to the December 1977 proposal discussed at length the basis on which the upper time limit was established. The purpose of having a maximum interval for the timer is to reduce the chance of severe erythema whereby medical attention is necessary. A 10-minute maximum timer interval was selected as one that would provide adequate protection and effectiveness when used with currently available sunlamps. This timer interval is consistent with the Underwriters Laboratory Standard (UL-482), and it also takes into account the lamp warmup time. The concept of graded timer interval was considered earlier, but it was not adopted because it would be more complex and, therefore, more difficult to implement.

The agency believes that both negative and positive error limits for the maximum timer interval are necessary for scale accuracy to deliver a desired exposure to the user. The consumer must have confidence in the timer scale for all time intervals less than 10 minutes. Also, the agency believes that the maximum timer interval should correspond to the maximum exposure time recommended by the manufacturer or to 10 minutes, whichever is less. Therefore, § 1040.20(c)(2)(ii) is issued as proposed.

11. One comment stated that the requirement for an extra manual control (switch) to activate the lamp (§ 1040.20(c)(4)) is unnecessary because, unless the timer resets itself automatically, the cumulative exposure time could not exceed 10 minutes.

The agency considers manual control for the resumption of radiation emission to be a necessary safety feature because better user control of exposure time is provided. The means that the manufacturer may use for implementing this performance criterion are not established by the requirement, and a separate switch per se for resumption of radiation is not required. The control features in §1040.20(c)(2), (3), and (4) may all be built into the timer. Alternatively, the manufacturer may use any other configuration of timer and switches to meet these requirements. Section 1040.20(c)(4) is clarified to include explicitly the applicability of the requirement to timers.

12. The preamble of the December 1977 proposal encouraged comments concerning the transmission of visible radiation through protective eyewear. Several comments stated that the protective eyewear required in proposed §1040.20(c)(5) should transmit enough visible light to enable the user to read the labels, set the timer, and perform other critical functions. Other comments stated that 2 percent transmission of visible light, as proposed in §1040.20(c)(5)(ii), was too low a value for adequate vision. Also, several comments suggested that the language of the Underwriters Laboratory Standard (UL-482) paragraph 14.3, be used. This states: "The goggle lenses shall allow sufficient transmission of visible light emitted from the sunlamp to enable the user to see clearly enough to reset the timer in a darkened room."

The agency agrees that the protective eyewear should transmit enough visible radiation to allow the user of the product to see to perform critical functions in a darkened room. The proposed specific upper limit of 0.02 for spectral transmittance of the protective eyewear for radiation of wavelengths greater than 360 nm is arbitrary. Therefore, § 1040.20(c)(5)(ii) is changed to be consistent with the Underwriters Laboratories requirement for transmission of visible radiation through the protective eyewear. However, as a guide, the protective eyewear should not transmit hazardous levels of visible radiation when the wearer looks directly toward the lamp from the minimum use distance.

13. One comment objected to the requirement that multiple sets of protective eyewear be supplied if the manufacturer recommends that a sunlamp be used by more than one person at a time (§ 1040.20(c)(5)(i)), because extra sets of eyewear are offered for sale if the customer believes they will be needed. The comment asserted that the effect of the requirement will be increased consumer prices with no corresponding benefit because many users already have protective eyewear.

The agency regards the requirement of §1040.20(c)(5)(i) as useful and consistent with the agency's desire to provide to the users the performance features they need to reduce the radiation hazard from sunlamps. This is especially true when the manufacturer recommends that the product be used by more than one person at a time. Further, a would-be purchaser of a sunlamp product would not necessarily have protective eyewear. The comment is rejected.

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14. There were many strongly worded objections to the proposal from dermatologists and from people afflicted with psoriasis. Their objections were directed primarily to proposed § 1040.20(c)(6)(iii), which would have prohibited any lamps subject to the standard from fitting a "medium bipin" lampholder described in the national consensus standard issued by the American National Standards Institute (ANSI C81.20-1976). The comments claimed that, if the proposed rule were promulgated, the leading manufacturer of fluorescent sunlamps (which fit the medium bipin lampholder) might cease producing them, and the result would be great hardship for many who use fluorescent sunlamps for the treatment of dermatological disorders such as psoriasis.

The agency is sympathetic to these comments and does not desire to have the fluorescent sunlamp removed from the market. Nor was that the intent of the proposal. The rule applies to sunlamps used for tanning; it is not intended to apply to fluorescent sunlamps used for medical treatment of dermatological disorders or for industrial or agricultural uses. Proposed § 1040.20(c)(6) is intended to prevent use of tanning sunlamps in lampholders used for general illumination that are commonly accessible to users at home and other places. Thus, it would ensure that sunlamps are used only in fixtures with appropriate timers, controls, and warning labels.

Revised sales and marketing information supplied by the leading manufacturer of fluorescent sunlamps in its comments on the proposal indicates that the annual sales volume of fluorescent sunlamps is about 31,000 units, of which 1 percent are used for skin-tanning purposes and 1 percent for medical prescription purposes in the home; 68 percent are used in health clubs, gymnasiums, etc.; and 30 percent are used in hospitals, in medical practice, and for industrial and agricultural purposes. Therefore, the proposed § 1040.20(c)(6)(iii) would have only a small effect upon the safety performance of sunlamp products used in the home, but would impose excessive retrofitting costs upon existing commercial suntanning, medical, industrial and agricultural facilities when the sales distribution of fluorescent sunlamps is considered. The agency has concluded that the benefit of the proposed provision does not offset the disadvantages. Thus, the requirement that an ultraviolet lamp may not be capable of insertion and operation in the medium bipin lampholder is deleted from the final order.

15. Several comments objected to the quantity and the repetitiveness of the information required by §§ 1010.2, 1010.3, 1040.20 (d) and (f), and Part 801 for the ultraviolet lamp, sunlamp product, and user instructions. Some comments noted that ultraviolet lamps are of special concern because it may be impossible to put all of the required information on the lamps. Others noted that the printing on a lamp is nearly invisible when the lamp is operating. One manufacturer suggested that labeling requirements for ultraviolet lamps be deleted entirely and that appropriate warnings in accompanying instructions be suggested in the preamble of the final regulation. Other manufacturers suggested simplified warning statements for the products. One comment stated that mere repetition of any required warning statements would generally be ineffective.

The agency believes that users of a sunlamp product and ultraviolet lamps should have the information necessary to make informed decisions regarding the risks of using the product. This principle requires appropriate product labeling and instructions for use.

The agency believes, however, that the amount of information originally proposed to be on the ultraviolet lamp can be reduced and the mode of display simplified without compromising public health and safety. The requirement of a label for certification and a label for the name and address of the manufacturer (21 CFR 1010.2 and 1010.3) can be satisfied by having tags or labels containing the information permanently affixed on the packaging for each lamp, if the name of the manufacturer and date of the manufacture are on the lamp for purposes of identification. The name of the manufacturer and the date of manufacture appearing on the lamp may be shortened by use of a code or symbols if the manufacturer has supplied the Director, Bureau of Radiological Health, with the key to the code or symbols and the location of the information on the lamp. Thus, the introductory text of § 1040.20(d) is changed and a new § 1040.20(d)(3) is added to incorporate these less restrictive concepts.

The agency also believes that the information required by the final rule to be on the sunlamp product is the minimum needed for the user to make informed decisions concerning the risks and proper use of the lamp in the absence of user instructions. User instructions can be more extensive and more detailed, at the option of the manufacturer. There is no certainty that the user instructions provided under § 1040.20(f) will always be with the product. Also, the publication of suggestions for the content of users' instructions in the preamble of the final rule is not appropriate. After publication, the preamble is not retained as part of the regulation in the Code of Federal Regulations (CFR). The information required by

§ 1040.20(d)(1) is not redundant to that required to be on the ultraviolet lamp (§ 1040.20(d)(2)). Thus, the comments objecting to the sunlamp product label requirements are rejected.

16. Several comments on § 1040.20(d)(1)(i) stated that all skin cancer tests have been performed with broad spectral sources and that the erythemal wavelengths alone are responsible for skin cancer. The comments stated that the fluorescent sunlamp has a relatively narrow spectral distribution, and there is no evidence that skin cancer has been caused by a fluorescent sunlamp. The comments expressed concern that reference to skin cancer could lead to unjustified litigation that would place the responsibility for any skin cancer on a sunlamp product and not on the other causes that cannot be identified.

The agency rejects the comment. The wavelength range of the radiation emitted by a fluorescent sunlamp is included in the wavelength ranges that are known to be associated with the induction of skin cancer. Radiation of erythemal wavelengths is also present in solar radiation, which is known to be associated with the appearance of skin cancer although the detailed action spectrum for cancer production in the ultraviolet region of the spectrum is not known. The inference that cancers are induced only in the presence of ultraviolet radiation of broad spectral distribution and not by radiation in the narrower erythemal spectrum has not been demonstrated. Therefore, this reference to skin cancer is justified, and the required warning is retained in this final rule.

17. Several comments on proposed § 1040.20 (d) and (f) concerned the harshness of required labels and instructions and asserted that no skin cancer has ever been observed in humans that could be attributed to the use of sunlamps, while agreeing that exposure of the skin to natural sunlight over many years can cause skin cancer. The comments expressed particular difficulty in understanding why FDA is insisting on the reference to cancer when it has not seen fit to impose any reference to cancer in labeling of cigarettes. One manufacturer suggested that, if caution labels and instructions along these lines are needed, then the concept of repeated overexposure should be added because there is no link to the harmful effects from just "exposure" to sunlamp radiation. Another manufacturer urged that the similarity of sunlamp radiation to that of the sun be emphasized. Alternative wording of some of the warning statements was suggested. Another comment stated that the wording in § 1040.20(f) (1) and (2) and the repetition of the warning, as required, will unfairly alarm people and will deter the use of sunlamps.

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The agency notes that sunlamps can produce erythema and that radiation of erythemal wavelength is present in solar radiation, which is known to be associated with the appearance of skin cancer. Warning labels and instructions for sunlamp products are necessary when the hazards of exposure to ultraviolet radiation are considered. Also, the label required by § 1040.20(d)(1)(i) warns the user of the similarity between sunlamp radiation and solar radiation. The overexposure to ultraviolet radiation in a single incident leads to acute effects such as skin burn and eye irritation (photokeratitis). Repeated exposure (chronic) may lead to premature skin aging and cancer. The warning labeling and instructions are believed to be sufficient. The agency also believes that the wording of the labels is accurate and understandable, so that the majority of the readers will comprehend the significance of the warnings. Finally, the agency advises that the health aspects of cigarettes and the appropriate warning labeling are not the subject of this particular agency action. The comments do not justify a change in the regulation and are rejected.

18. A comment stated that phrases such as "minimum use distance" and "recommended maximum exposure time" are ambiguous because exposure sequence, skin sensitivity, and customer use vary considerably. In contrast, flexibility in the writing of instructions would result in greater customer awareness of any recommended pre-

cautions. The comment urged that § 1040.20(d)(1) be revised to eliminate the discussed phrases.

The agency notes that both "minimum use distance" and "maximum exposure time" are defined in § 1040.20(b) and are values recommended by the manufacturer of each sunlamp product. A recommended value for "minimum use distance" and "maximum exposure time" is useful, for example, for the person being exposed for the first time after a long interlude or for the sensitive person but should not be relied upon by persons suffering from diseases such as xeroderma pigmentosum, erythropoietic porphyria, or lupus erythematosis. The "minimum use distance" and "maximum exposure time" are required to be specified by the manufacturer, who must determine the most appropriate values for the product. Supplemental information can be provided if the manufacturer believes the required information to be inadequate for the product. The agency is amending § 1040.20 (b)(5) and (d)(1) to make clear and to emphasize that recommended values of "minimum use distance" and "maximum exposure time" must be provided.

19. A comment stated that the labeling required in § 1040.20, while required to be permanently affixed, is not clearly required to be legible throughout the product's useful life. A paper or plastic label may deteriorate from heat and remain permanently affixed but not be legible. Another comment suggested that any label warning should be in contrasting color to draw attention to it. The comment noted that colors for labels were not specified in § 1040.20(d), although reproductions of the labels in the instructions are explicitly "color optional."

Products subject to the performance standards promulgated under the authority of the Radiation Control for Health and Safety Act of 1968 must comply with the standards during their entire useful life. The labels required for the sunlamp product must be legible and permanently affixed. Hue, intensity, contrast, and size of the wording on a label with the background are part of the legibility concept. Reproductions in user instructions of the required labels are permitted to be in colors chosen by the manufacturer because, if the reproductions were required to be the same color as on the product, the cost of the user information brochure could be increased needlessly. The agency has clarified § 1040.20(d) regarding label specifications.

20. Several comments objected to the complexity of the summary listing of deleterious effects required by § 1040.20(f) on the ground that manufacturers should not be expected to maintain current knowledge of every possible deleterious effect from ultraviolet radiation.

The agency believes that the manufacturer of a product has an obligation to inform the user, as well as the purchaser, of the known deleterious effects associated with the product. The proposed standard contained a current list of selected known deleterious effects in § 1040.20(f) (1)(iii) and (2)(iii). However, the agency believes the simplified statements included in the warning required by § 1040.20 (d)(1)(i), (f) (1)(ii) and (2)(ii) are adequate and will be more effective; thus, § 1040.20(f) (1)(iii) and (2)(iii) are deleted.

21. One comment suggested that all ultraviolet lamps, regardless of their purpose, carry the instructions specified in § 1040.20(f)(2). This would reduce the probability that ultraviolet lamps outside the definition of § 1040.20(b)(11) might be used for tanning and would eliminate the need for a new lampholder design, permitting the present standardization of lampholder designs to be continued. Another comment suggested that a technical brochure providing complete application and safety information should be made available and packed with each six-lamp container.

The agency rejects these comments. The first suggested action is too broad; thus, the warning would be placed on lamps used in situations where no hazard to humans is posed. The purpose of the base requirement of § 1040.20(c)(6) is to force the use of ultraviolet lamps in lampholders that comply with the other requirements of the standard. Regarding the second suggestion, safety information packed with each six-lamp container would probably not be available to the user because most users in the home buy only one lamp at a time.

Manufacturers of all sunlamp products and ultraviolet lamps intended for use in sunlamp products are currently subject to the records and reports requirements under § 1002.61(a)(4). On the effective date of this final rule, those intended for skin tanning will be included automatically in § 1002.61(c)(1), which concerns products subject to standards prescribed under 21 CFR Chapter I, Subchapter J. To conform the regulations concerning records and reports, § 1002.61(a)(4) is amended to delete any reference to sunlamps and ultraviolet lamps intended to induce skin tanning.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (secs. 358 and 360a, 82 Stat. 1177-1179, 1182 (42 U.S.C. 263f and 263i)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Chapter I, Subchapter J of Title 21 of the Code of Federal Regulations is amended as follows:

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§ 1002.61

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§ 1040.20

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[FR Doc.79-34635 Filed 11-8-79; 8:45 am]

VI. Sonic, Infrasonic and Ultrasonic Radiation-Emitting Products

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†D. Ultrasonic Products

†5.—Diagnostic Ultrasonic Equipment Performance Standards

†5.1 Notice of Intent—February 13, 1979

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[21 CFR Subchapter J]

[Docket No. 78N-0288]

DIAGNOSTIC ULTRASOUND EQUIPMENT

Intent to Propose Rules and Develop Recommendations

AGENCY: Food and Drug Administration.

ACTION: Notice of Intent.

SUMMARY: The Food and Drug Administration (FDA) is considering an action program for diagnostic ultrasound equipment, including that used to visualize and monitor the fetus during pregnancy and labor. The agency may develop recommendations or mandatory performance standards related to diagnostic ultrasound equipment or may require manufacturers to supply purchasers with performance data and other information related to safety. One or more actions could follow, including recommended user procedures, recommended training criteria for users, recommendations covering equipment performance, manufacture and test procedures, regulatory product performance standards, and/or informational requirements. Before beginning this program, the agency is requesting further information and is inviting comments on conceptual criteria for users and for manufacturers of diagnostic ultrasound equipment.

DATES: Comments and data by August 13, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Melvyn R. Altman, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD

20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration, through the Bureau of Radiological Health (BRH) and under the authority of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.), administers an electronic product radiation control program. This authority provides for the protection of the public health and safety through development and administration of radiation safety performance standards and development of recommendations for controlling electronic product radiation. The Food and Drug Administration also has authority under the Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device Amendments of 1976 (Pub. L. 94-295; 90 Stat. 539-583 (21 U.S.C. 360c et seq.)) regarding safety and effectiveness of medical diagnostic ultrasound equipment.

The Commissioner recognizes the demonstrated benefit of the use of diagnostic ultrasound in neurology, cardiology, obstetrics and gynecology, ophthalmology, and other fields of clinical medicine. Although ultrasound is now widely accepted as an indispensable diagnostic tool, the possible risks associated with diagnostic ultrasound are not fully understood. To date there have been no reports of adverse effects associated with the clinical use of diagnostic ultrasound, but clinical impressions, although valuable, do not establish conclusively that the use of diagnostic ultrasound involves no risks. Past human epidemiological studies have yielded inconclusive evidence, and it will probably be several years before definitive data will be available from current and future epidemiological studies. Thus, laboratory studies on animals must be used as indicators of possible adverse biological effects in humans.

Many of the early animal studies utilized ultrasound intensities that were well above diagnostic intensities and examined endpoints which were often representative of only gross pathological damage. However, recent reports of biological effects in animals exposed to ultrasound have involved levels of ultrasound representative of current diagnostic ultrasound applications (Ref. 1). It may be argued that many of the studies do not represent the exact exposure conditions of the clinical situations, or that the dosimetry is imperfect, or that the data have not been verified by other investigators, or that most of the data involve continuous wave exposure. However, the Commissioner believes that not all such studies can be dismissed as irrelevant, particularly because some of the studies involve the use of clinical devices.

Because of the extent of use of diagnostic ultrasound procedures during pregnancy and the recognized susceptibility of embryonic tissue to a variety of insults, those studies indicating that ultrasound can effect the development of laboratory animals exposed in utero are of particular concern. Some of the reported effects include delayed neuromotor reflex development (Ref. 2), altered emotional behavior (Ref. 3), and fetal anomalies in rodents exposed to clinical diagnostic ultrasound devices with reported acoustic outputs ranging from 20 milliwatts per square centimeter (mW/cm^2) to 40 mW/cm^2 (spatial and temporal-average intensities) (Ref. 4).

An examination of the current literature suggests that some of the most sensitive indicators of ultrasound-induced alterations appear to be associated with the central nervous system. These reported effects include increased levels of an enzyme (glutamic oxaloacetic transaminase) in the cerebrospinal fluid of dogs (Ref. 5) and induced electrical activity in the brain (evoked electroencephalographic responses) of nonhuman primates (Ref. 6) after exposure to ultrasound from diagnostic instruments with reported acoustic spatial and temporal-average intensities of 1.5 mW/cm^2 and 3 mW/cm^2 respectively.

How the available bioeffects data translate into risk to humans exposed to ultrasound is not clear at this time. There have been attempts to use the available data, both positive and negative, to construct curves or limits that delineate threshold levels or lowest levels for significant biological effects (Refs. 7, 8, and 9). Such levels have been widely interpreted as representing "safe" levels of ultrasound. However, the Commissioner does not believe such graphic analyses of isolated bioeffect data, most of which represent studies not designed to measure threshold effects, can define a safe region. It will probably be several years before the risks of diagnostic ultrasound to humans can be established and quantified. Because human studies of adverse effects from ultrasound have been inadequate, there is no direct way at this time to establish the exposure limits that assure safety in the use of this modality. Thus, the Commissioner believes manufacturers should not state in advertising or promotional literature that diagnostic ultrasound is unequivocally safe.

In view of reports of biological effects in laboratory animals after exposure to ultrasound at intensities representative of those used in a diagnostic applications (Ref. 1) and a report of increased movement of the human fetus during examination with clinical diagnostic ultrasound (Ref. 10), the Commissioner believes an individual's exposure to ultrasound should be kept as low as practicable, consistent with obtaining essential diagnostic information. Also, ultrasound exposure of pregnant humans for commercial demonstration of equipment is not considered acceptable by most professional organizations in the field.

The Commissioner is also concerned about the rapidly growing use of this modality while definitive information on biological effects is lacking. In recent years ultrasound radiation has become a common diagnostic tool in many widely varied medical specialties. The types of devices used in diagnostic medicine include pulse-echo imaging devices, continuous-wave Doppler units, pulse devices, and transmission equipment. One study has advocated that diagnostic ultrasound be used as a routine screening practice in all pregnancies (Ref. 11). The Obstetrical and Gynecological Device Classification Panel recommended that physicians not use this modality indiscriminately. However, the extent to which exposure to ultrasound radiation actually occurs will depend on whether available equipment is actually used in obstetrics and whether marketing forecasts are valid.

Several investigators have measured acoustic intensity levels from commercial diagnostic pulse-echo devices. The results of these limited studies indicate that the spatial and temporal-average intensities for most available pulse-echo devices are less than 10 mW/cm^2 (Ref. 12). However, there is currently no way to assure that all equipment will operate at these levels. For example, a report submitted by a manufacturer to BRH indicates that time-average intensity output of approximately 80 mW/cm^2 can be expected from the manufacturer's pulse-echo equipment. Clearly, output levels of pulse-echo devices can vary widely without operator knowledge.

Similar variation can occur with continuous-wave Doppler devices (Ref. 13). One investigator has reported that obstetrical continuous-wave Doppler devices can be designed to operate at ultrasonic intensities below 5 mW/cm^2 (Ref. 14). Here again, widely varying outputs of similar devices designed to obtain the same medical information have been observed. It may be desirable to discourage marketing of equipment with higher intensity capabilities, unless they are justified on the basis of needed improvement in diagnostic capability. With regard to Doppler units, it is important to consider that exposure times can range from less than 1 minute to periods of several hours, as in the case of fetal monitoring during labor and delivery.

From these examples, the Commissioner, in accord with recommendations of the Obstetrical and Gynecological Device Classification Panel, believes it prudent to use the lowest practical exposure levels, consistent with obtaining needed diagnostic information, and to use diagnostic ultrasound only when there is a valid medical reason. In this respect, the Commissioner believes the proposed recommendations of the Technical Committee of the Ultrasound Section of the National Electrical Manufacturers Association (NEMA) for abdominal scanning (10 mW/cm^2 for pulse-echo devices) provide reasonable guidelines for the upper limits of spatial and temporal-average intensities that should be expected from these types of diagnostic ultrasound equipment (Ref. 19).

Information on acoustic emissions and imaging characteristics should be available to the user so that the user can make informed judgments regarding the use of this diagnostic modality. The Commissioner believes disclosure of output levels, as well as imaging characteristics, would aid the user in selecting equipment that would provide the desired diagnostic information while at the same time expose the patient to the lowest levels of ultrasonic radiation. Disclosure of imaging characteristics and output information would discourage claims that higher output necessarily implies more useful equipment. The Commissioner is considering requirements that output and imaging information be provided to users by manufacturers. In addition, user training activities are needed to eliminate unproductive exposure and to assure that consistently high quality diagnostic information is produced.

Several factors, including system sensitivity, resolution, gray scale dynamic range, registration, and calibration, directly affect the diagnostic capability of Doppler and/or pulse-echo equipment. Optimizing these factors can yield superior diagnostic information with minimum ultrasound exposure. Measurement surveys by FDA and other institutions indicate these factors vary widely among commercial models of diagnostic ultrasound equipment (Refs. 15 and 16). Other reports show that in the absence of routine testing and maintenance these factors vary with time for individual devices, and the informational quality of diagnostic ultrasound equipment will deteriorate (Refs. 17 and 18). The Commissioner is considering the promulgation of recommendations to users and/or equipment performance standards to improve this situation.

Because of these concerns and unresolved issues, BRH will continue to conduct biological effects investigations, evaluate equipment performance, and support research in these areas. Also, NEMA is considering ways to support biological effects studies. As in other problem areas (e.g., effects of ionizing radiation), no single study can provide all the necessary information. A program of collaborative research including well designed and executed studies is needed to determine the extent of risk to human health posed by exposure to diagnostic ultrasound. In addition to investigating biological effects, work will continue on developing methods to measure and evaluate the acoustic emissions and the imaging characteristics of diagnostic ultrasound equipment. The BRH will continue to measure and evaluate the performance of such equipment through laboratory tests and review of reports that manufacturers are required to submit as specified in §§ 1002.10 and 1002.12 (21 CFR 1002.10 and 1002.12). Current and future data will be evaluated relative to the development of recommendations and performance standards and BRH may obtain additional performance and other technical data from manufacturers. In addition, the Commissioner encourages ultrasound users to notify BRH of accidental overexposures and adverse reactions of patients and workers.

The Commissioner recognizes and encourages the constructive efforts of the industry and others towards the development of standards for safe and effective diagnostic ultrasound equipment. A joint project by NEMA and the American Institute of Ultrasound in Medicine (AIUM) may result in a voluntary safety performance standard for this equipment. In addition, the Acoustical Society of America is actively developing standards for diagnostic ultrasound devices. The Commissioner will carefully consider the results, if timely and effective, of these and other voluntary efforts before taking further action.

The Commissioner will consult one or more of the advisory committees concerned with the safety and effectiveness of diagnostic ultrasound devices—the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), the Medical Radiation Advisory Committee (MRAC), and appropriate medical device panels—concerning any further proposed action and any comments received in response to this notice. The TEPRSSC is a permanent statutory advisory committee to the Secretary of Health, Education, and Welfare and must be consulted before the establishment of standards under the Radiation Control for Health and Safety Act of 1968. The MRAC advises and consults with BRH in formulating policy and developing a coordinated program related to use of radiation in the healing arts. Medical device panels have been established under section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) to make recommendations to the Commissioner for the classification of medical devices for human use. The MRAC and TEPRSSC considered drafts of this notice at their respective meetings on May 8 through 10 and June 1 and 2, 1978. Both committees generally supported the plan to publish a notice of intent concerning diagnostic ultrasound. Earlier, the Obstetrical and Gynecological Device Classification Panel recommended that all diagnostic and monitoring ultrasound devices be classified in class II, performance standards.

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The following questions and conceptual criteria for users and manufacturers are provided for consideration and comment. Such criteria may be the subject of future proposed performance standards or voluntary recommendations under the acts administered by the agency.

QUESTIONS AND CONCEPTUAL CRITERIA RELATED TO THE CLINICAL USE OF DIAGNOSTIC ULTRASOUND EQUIPMENT

1. Diagnostic ultrasound should be used for human exposure only when there is a valid medical reason. Which of the following or what additional reasons should be considered valid (and under what conditions): medical diagnosis, patient or fetal monitoring, and educational and research applications approved by institutional review boards?

2. Users of diagnostic ultrasound equipment should have adequate training. How extensive should such training be? Should such training be only formalized training? Should it include instruction in both operator techniques and interpretation of diagnostic ultrasound information, instruction in performance measurements and procedures, and instruction in biological effects of ultrasound radiation?

3. Users of diagnostic ultrasound should implement adequate routine quality assurance programs to monitor equipment performance. What should be the elements of such programs? For example, should system sensitivity, depth calibration, and transducer resolution be periodically measured? What other measurements should be made?

QUESTIONS AND CONCEPTUAL CRITERIA RELATED TO THE MANUFACTURE OF DIAGNOSTIC ULTRASOUND EQUIPMENT

1. Manufacturer's specifications regarding ultrasound emissions as well as imaging effectiveness should be provided to the user. Which of the following or what additional parameters should be specified? (Items related to acoustic output defined in the proposed AIUM nomenclature (Ref. 20) are italicized):

a. Maximum and average ultrasound *intensity* in time and space;

b. Maximum and average ultrasound *power;*

c. Transducer pulse shape, *pulse duration,* and *pulse repetition rate;*

d. Transducer frequency spectrum information;

e. Transducer *beam pattern* (axial and transverse);

f. Transducer *focal length* and *focal zone;*

g. Area of transducer *beam cross-section* and *beam width* (at focal length, if focused);

h. Lateral resolution for each transducer;

i. Range resolution for each transducer (except for continuous-wave Doppler);

j. Sensitivity;

k. Position registration accuracy (for compound B-scan);

l. System dynamic range;

m. Range calibration accuracy (pulse-echo equipment).

2. Manufacturers should adopt quality control and testing programs adequate to assure that equipment per-

formance specifications are met and that information provided with equipment is accurate. What are the elements of an adequate testing program for the manufacture of diagnostic ultrasound equipment?

3. Ultrasonic equipment maximum output capabilities should be as low as practical, consistent with obtaining needed diagnostic information. Should there be a specific recommended or mandatory limit on equipment output? For example, such a limit might require that diagnostic ultrasound equipment not produce spatial peak, time-average intensities in excess of 100 mW/cm^2 unless the manufacturer can strongly justify such exposures based on needed improvement in diagnostic capability. Would such a limit discourage trends to increased equipment output? Would such a limit be viewed as a "perfectly safe" level?

4. Diagnostic ultrasound should be used for human exposure only when there is a valid reason for its use. Are there any valid reasons for exposure of living humans to diagnostic ultrasound for purposes of commercial demonstration?

Persons or organizations wishing further information made public on the development of the action program for ultrasound diagnostic equipment and its use may write to the contact person whose address appears in the heading of this notice.

The following references are on file at the office of the Hearing Clerk, FDA, and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday:

(1) Stratmeyer, M. E., "Research Directions in Ultrasound Bioeffects—A Public Health View," Symposium on Biological Effects and Characterizations of Ultrasound Sources, June 2 and 3, 1977, pp. 240-245, HEW Publication (FDA) 78-8044.

(2) Murai, N., K. Hoshi, and T. Nakamura, "Effects of Diagnostic Ultrasound Irradiated During Fetal Stage on Development of Orienting Behavior and Reflex Ontogeny in Rats," *Tohoku Journal of Experimental Medicine*, 116:17-24, 1975.

(3) Murai, N., K. Hoshi, C. Kang, and M. Suzuki, "Effects of Diagnostic Ultrasound Irradiated During Fetal Stage on Emotional and Cognitive Behavior in Rats," *Tohoku Journal of Experimental Medicine*, 117:225-235, 1975.

(4) Shoji, R., E. Momma, T. Shimizu, and S. Matsuda, "An Experimental Study on the Effects of Low Intensity Ultrasound on Developing Mouse Embryos," *Teratology*, 6:119, 1972.

(5) Tsutsumi, Y., K. Sano, T. Kuwabara, T. Takakura, K. Hayakawa, T. Suzuki, and M. Katanuma, "A New Portable Echo-Encephalograph, Using Ultrasonic Transducers; and its Clinical Application," *Medical Electronics and Biological Engineering*, 2:21-29, 1964.

(6) Hu, J. H. and W. D. Ulrich, "Effects of Low-Intensity Ultrasound on the Central Nervous System of Primates," *Aviation, Space, and Environmental Medicine*, 47:640-643, 1976.

(7) Nyborg, W. L., "Physical Mechanisms for Biological Effects of Ultrasound," report based on series of lectures presented March 12 to April 2, 1976, at the Bureau of Radiological Health, HEW Publication (FDA) 78-8062.

(8) Ulrich, W. D., "Ultrasound Dosage for Experimental Use on Human Beings," Naval Medical Research Institute Research Report, Proj. M4306, 01-101-0 BXXO, Report #2, August 18, 1971.

(9) Wells, P. N. T., "The Possibility of Harmful Biological Effects in Ultrasound Diagnosis," *in* "Proceedings of Symposium on Cardiovascular Applications of Ultrasound," Beese, Belgium, May 29 and 30, 1973.

(10) David, H., J. B. Weaver, and J. F. Pearson, "Doppler Ultrasound and Fetal Activity," *British Medical Journal*, 2:62-64, 1975.

(11) Donald, I., "New Problems in Sonar Diagnosis in Obstetrics and Gynecology," *American Journal of Obstetrics and Gynecology*, 118:299-309, 1974.

(12) Stewart, H. F., G. R. Harris, and H. M. Frost, "Development of Principles and Concepts for Specification of Ultrasonic Diagnostic Equipment Performance," *Ultrasound in Medicine*, Vol. 3B, Edited by Dennis White and Ross Brown, Plenum Press, pp. 2115-2142, 1977.

(13) Rooney, J. A., "Determination of Acoustic Power Outputs in the Microwatts-Milliwatts Range," *Ultrasound in Medicine and Biology*, 1:1-4, 1973.

(14) Ziedonis, J. G., "Ultrasonic Power Levels Used in Commercial Equipment for Medical Applications and How to Control It for Patients Safety," Proceedings of the Society of Photo-Optical Instrumentation Engineers, 47:110-111, Aug. 1 and 2, 1974.

(15) Christensen, S. L. and P. L. Carson, "Performance Survey of Ultrasound Instrumentation and Feasibility of Routine Monitoring," *Radiology*, 122:449-454, 1977.

(16) Erickson, K. R., P. L. Carson, and H. F. Stewart, "Field Evaluation of the AIUM Standard 100 mm Test Object," *Ultrasound in Medicine*, Vol. 2, Edited by White and Barnes, Plenum Press, New York, 1976.

(17) Goldstein, A., "Gray Scale Shifts in Ultrasound Displays," *Radiology*, 121:175-162, 1976.

(18) Smith, S. W., H. Lopez, and H. F. Stewart, "Methods and Results of Dynamic Range Testing of Diagnostic Ultrasound Instrumentation," Proceedings of the Society of Photo-Optical Instrumentation Engineers (in press).

(19) Technical Committee of the Ultrasound Section of the Radiation Imaging Products Division, National Electrical Manufacturers Association, "Recommendations of the Technical Committee Proposed for Consideration," submitted to the Ultrasound Subcommittee of the BMD OB/Gyn Device Classification Panel, October 22, 1976.

(20) Proposed American Institute of Ultrasound in Medicine (AIUM) Nomenclature, Fifth Draft, August 21, 1977.

This notice of intent is issued under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (secs. 356 and 358, 82 Stat. 1174-1179 (42 U.S.C. 263d and 263f)); the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 301 et seq.); and authority delegated to the Commissioner (21 CFR 5.1).

Interested persons are invited to participate in the development of an action program by submitting written comments, views, and data on the subject. Communications should reference the docket number appearing in the heading of this document and should be sent to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, by August 13, 1979. Timely comments will be considered in formulating the action program. Comments received after the closing date may be considered, depending on the stage of development of any standards or recommendations.

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[FR Doc. 79-4659 Filed 2-12-79; 8:45 am]

REDESIGNATION TABLES

At 38 FR 1933, January 19, 1973, regulations pertaining to radiological health under Part 78 of Title 42 of the Code of Federal Regulations were transferred to the newly established Part 278 of Title 21 of the Code of Federal Regulations.

At 38 FR 28624, October 15, 1973, Part 278 was transferred and recodified as Subchapter J—Radiological Health, now comprising Parts 1000 through 1090.

The following tables show the relationship of the CFR section numbers under former 42 CFR Part 78 and 21 CFR Part 278 to the new Subchapter J—Radiological Health (Table 2), and the relationship of the current CFR section numbers under Subchapter J to the former designations (Table 1).

RADIOLOGICAL HEALTH

TABLE 1

New Section	Old Section		Preamble Compilation Designation
	21 CFR	42 CFR	
1000.3	278.100	78.100	I.A.1, I.A.3
1000.14	(proposal)	(proposal)	I.G.15
1000.15	278.101	78.101	I.A.1
1000.16	278.102*	NA	III.E.10, III.E.11
1000.16	278.103*	NA	III.E.10, III.E.11
1000.50	NA	NA	I.C.25
1000.51	(proposal)	(proposal)	I.C.5
1000.55	NA	NA	I.C.10
1000.60	(proposal)	(proposal)	I.C.3,I.C.35
1002.1	278.701	78.701	I.G.1,I.G.10
1002.2	278.702	78.702	I.G.1
1002.3	278.703	78.703	I.G.1
1002.4	278.713	78.713	I.G.1
1002.10	278.710	78.710	I.G.1,I.G.5,I.G.10,I.G.55
1002.11	278.712	78.712	I.G.1
1002.12	278.711	78.711	I.G.1
1002.20	278.705	78.705	I.G.1
1002.30	278.720	78.720	I.G.1
1002.31	278.721	78.721	I.G.1
1002.40	278.730	78.730	I.G.1,I.G.15
1002.41	278.731	78.731	I.G.1,I.G.15
1002.42	278.732	78.732	I.G.1
1002.50	278.740	78.740	I.G.1
1002.51	278.741	78.741	I.G.1,I.G.10
1002.61	278.750	78.750	I.G.1,I.G.45,I.G.50,I.G.55
1003.1	278.500	78.500	I.A.1
1003.2	278.501	78.501	I.A.1
1003.5	278.514	78.514	I.A.1
1003.10	278.502	78.502	I.A.1,I.A.3
1003.11	278.508	78.508	I.A.1
1003.20	278.503	78.503	I.A.1
1003.21	278.504	78.504	I.A.1,I.A.3
1003.22	278.505	78.505	I.A.1
1003.30	278.506	78.506	I.A.1
1003.31	278.507	78.507	I.A.1
1004.1	278.509	78.509	I.A.1
1004.2	278.510	78.510	I.A.1
1004.3	278.511	78.511	I.A.1
1004.4	278.512	78.512	I.A.1
1004.6	278.513	78.513	I.A.1
1005.1	278.601	78.601	I.A.1,I.E.15

RADIOLOGICAL HEALTH—Continued

TABLE 1

New Section	Old Section		Preamble Compilation Designation
	21 CFR	42 CFR	
1005.2	278.602	78.602	I.A.1
1005.3	278.603	78.603	I.A.1
1005.10	278.604	78.604	I.A.1
1005.11	278.605	78.605	I.A.1
1005.20	278.606	78.606	I.A.1
1005.21	278.607	78.607	I.A.1
1005.22	278.608	78.608	I.A.1
1005.23	278.609	78.609	I.A.1
1005.24	278.610	78.610	I.A.1
1005.25	278.630	78.630	I.A.1,I.E.5,I.E.15
1010.1	278.200	78.200	IV.J.1,V.D.1
1010.2	278.201	78.201	I.B.1,I.G.15,IV.J.1,V.D.1
1010.3	278.202	78.202	I.B.2,I.G.5,I.G.15,IV.J.1,V.D.1
1010.4	NA	NA	II.D.1
1010.5	NA	NA	II.E.1
1010.13	278.203	78.203	IV.J.1,V.D.1
1010.20	278.204	78.204	IV.J.1,V.D.1
1020.10	278.210	78.210	IV.J.1
1020.20	278.211	78.211	IV.C.1
1020.30	278.213-1	78.213-1	II.D.1,III.E.1,III.E.2,III.E.4,III.E.11,III.E.8, III.E.13,III.E.15,III.E.17,III.E.30
1020.31	278.213-2	78.213-2	III.E.1,III.E.2, III.E.8, III.E.13,III.E.15,III.E.30
1020.32	278.213-3	78.213-3	II.E.1,III.E.2, III.E.8, III.E.13,III.E.30
1020.40	278.214*	NA	III.C.1
1030.10	278.212	78.212	IV.G.1,IV.G.2,IV.G.7,IV.G.9
1030.20	(proposal)	(proposal)	IV.F.1
1040.10	NA	NA	V.D.1, V.D.2
1040.11	NA	NA	V.D.1, V.D.2
1040.20	(proposal)	(proposal)	V.G.1
1040.30	NA	NA	V.E.1
1050.10	NA	NA	VI.E.1
1090.400	NA	NA	I.A.6

*Proposed before recodification.

Table 2

Old Section	New Section		Preamble Compilation Designation
42 CFR	42 CFR	21 CFR	
78.100	278.100	1000.3	I.A.1
78.101	278.101	1000.15	I.G.1
NA	278.102*	1000.16	III.E.10,III.E.11
NA	278.103*	1000.16	III.E.10,III.E.11
78.200	278.200	1010.1	IV.J.1,V.D.1
78.201	278.201	1010.2	I.B.1,I.G.15,IV.J.1,V.D.1
78.202	278.202	1010.3	I.B.2,I.G.5,I.G.15,IV.J.1,V.D.1
78.203	278.203	1010.13	IV.J.1,V.D.1
78.204	278.204	1010.20	IV.J.1,V.D.1
78.210	278.210	1020.10	IV.J.1
78.211	278.211	1020.20	IV.C.1
78.212	278.212	1030.10	IV.G.1,IV.G.2,IV.G.7,IV.G.9
78.213-1	278.213-1	1020.30	II.D.1,III.E.1,III.E.2,III.E.4,III.E.11,III.E.8, III.E.13,III.E.15,III.E.30
78.213-2	278.213-2	1020.31	III.E.1,III.E.2,III.E.8,III.E.13,III.E.15,III.E.30
78.213-3	278.213-3	1020.32	III.E.1,III.E.2,III.E.8,III.E.13,III.E.30
NA	278.214*	1020.40	III.C.1
78.500	278.500	1003.1	I.A.1
78.501	278.501	1003.2	I.A.1
78.502	278.502	1003.10	I.A.1,I.A.3
78.503	278.503	1003.20	I.A.1
78.504	278.504	1003.21	I.A.1,I.A.3
78.505	278.505	1003.22	I.A.1
78.506	278.506	1003.30	I.A.1
78.507	278.507	1003.31	I.A.1
78.508	278.508	1003.11	I.A.1
78.509	278.509	1004.1	I.A.1
78.510	278.510	1004.2	I.A.1
78.511	278.511	1004.3	I.A.1
78.512	278.512	1004.4	I.A.1
78.513	278.513	1004.6	I.A.1
78.514	278.514	1003.5	I.A.1
78.601	278.601	1005.1	I.A.1,I.E.15
78.602	278.602	1005.2	I.A.1
78.603	278.603	1005.3	I.A.1

Table 2—Continued

Old Section	New Section		Preamble Compilation Designation
42 CFR	42 CFR	21 CFR	
78.604	278.604	1005.10	I.A.1
78.605	278.605	1005.11	I.A.1
78.606	278.606	1005.20	I.A.1
78.607	278.607	1005.21	I.A.1
78.608	278.608	1005.22	I.A.1
78.609	278.609	1005.23	I.A.1
78.610	278.610	1005.24	I.A.1
78.630	278.630	1005.25	I.A.1,I.E.5,I.E.15
78.701	278.701	1002.1	I.G.1,I.G.10
78.702	278.702	1002.2	I.G.1
78.703	278.703	1002.3	I.G.1
78.705	278.705	1002.20	I.G.1
78.710	278.710	1002.10	I.G.1,I.G.5,I.G.10,I.G.55
78.711	278.711	1002.12	I.G.1
78.712	278.712	1002.11	I.G.1
78.713	278.713	1002.4	I.G.1
78.720	278.720	1002.30	I.G.1
78.721	278.721	1002.31	I.G.1
78.730	278.730	1002.40	I.G.1,I.G.15
78.731	278.731	1002.41	I.G.1,I.G.15
78.732	278.732	1002.42	I.G.1
78.740	278.740	1002.50	I.G.1
78.741	278.741	1002.51	I.G.1,I.G.10
78.750	278.750	1002.61	I.G.1,I.G.15,I.G.55

*Proposed before recodification.

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